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Describing and understanding patient safety incidents in primary care dentistry and building consensus on never events

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Abstract

Introduction: In recent decades, there has been considerable international attention directed towards minimising healthcare-associated harm and improving the safety of hospital care. More recently, this attention has broadened to include primary medical care. In 2002, the World Health Assembly recognised the issue of inadequate levels of patient safety as a major threat to global public health. In the following years, many countries have developed national strategies for the measurement, monitoring and prevention of patient safety incidents (PSIs) and their outcomes. Experience accumulated from secondary care has shown that the initial steps for understanding patient safety include the systematic identification of the most frequent and most harmful threats. However, the safety profile of primary care dentistry remains poorly investigated. As a result, current evidence cannot provide reliable estimates of the types of PSIs in primary care dentistry, the causes of these incidents, or the associated disease burden caused by such incidents.

In medicine, improvements in patient safety were achieved at a national level by developing a shared conceptual understanding, the standardisation of terminology and through preventive initiatives such as the introduction of a national incident reporting and learning system. In the United Kingdom (UK), the England and Wales' National Reporting Learning System (NRLS) has been an important source of insight, from the perspectives of the reporter, into understanding why PSIs occur. This initiative has led to the implementation of patient safety oriented policies to monitor and reduce cases of healthcare-associated harm. Examples of such policy initiatives include national guidelines and national safety recommendations to encourage the reporting of serious reportable events called 'never events' (NEs). These are defined as serious, preventable PSIs that should not occur if the available preventive measures are implemented. At a national level, serious incidents and NEs must be reported to the NRLS and/or other reporting systems. However, little is known about NEs in dentistry as wrong-tooth extractions are the only currently defined NE that has a clear application in dentistry. Although surgical NEs, such as wrong-site surgery and wrong implants may be related to dental procedures, these overlap with procedures conducted in secondary care. As a result, there is no agreed list of NEs for primary care dentistry.

The overall aim of my PhD was to explore patient safety, its concepts, including error and harm, and how these can help to create an understanding of the types of PSIs that occur in primary care dentistry, their contributory factors and their consequences. In addition, I also aimed to identify NEs with the greatest need and opportunity for future intervention strategies, in order to improve patient safety in primary care dentistry.

Methodology and methods: My PhD was conducted in three phases. For the first phase, I conducted a systematic scoping review of the empirical evidence published over a 20-year period (1994-2014). To achieve this, I searched MEDLINE and EMBASE for articles reporting incidents that could have or did result in unnecessary harm from primary dental care. I also extracted and synthesised data on the types and frequencies of PSIs (including NEs) and adverse outcomes. Then, for the second phase, I undertook an exploratory sequential mixed-methods evaluation, which involved the qualitative exploration and analysis of a weighted-by-year randomised sample (n=2,000) of the most severe incident reports from primary care dentistry submitted to the England and Wales' NRLS. This approach generated three coding frameworks, aligned to the International Classification for Patient Safety developed by the World Health Organization, for i) the classification of incidents, ii) contributory factors and iii) incident outcomes. These coding frameworks informed the quantitative analysis, during which myself together with a trained second coder, applied codes to deconstruct the narrative of these patient safety incident reports whilst retaining the meaning of the report. To assess inter-rater reliability, Cohen's Kappa statistic was calculated for the primary incident type which was defined as "the incident that resulted in the outcome experienced by the patient." Finally, for the third phase, I undertook an electronic Delphi exercise to achieve international agreement on NEs for primary care dentistry. The results obtained from Phases 1 and 2 were used to identify candidate NEs. I then invited an international panel of 41 experts to complete two rounds of questionnaires; 32 (78%) agreed to participate and completed the first round, and 29 (91%) completed the second round. I provided anonymised controlled feedback between rounds and used a cut-off of 80% agreement to define consensus. The results from the first stage built the evidence base for the second and third phases. Likewise, the results from the second phase further informed the third and final stage of my PhD.

Results: I undertook a systematic scoping review which demonstrated: a) there were considerable differences in definitions for terms used to describe patient safety, b) that a range of populations had been studied, and c) that major differences in sampling strategies exist between studies. The main five PSIs I identified were errors in i) diagnosis/examination, ii) treatment planning, iii) communication, iv) procedural errors and v) the accidental ingestion or inhalation of foreign objects. However, little attention has been paid to wider organisational factors such as problems within the physical environment, scheduling (e.g. errors in managing appointments) and patient access, management and lines of responsibility. Also there is very little evidence of interest in researching into the influence of policies for either quality or patient safety assurance. The retrieved evidence was used to build a conceptual literature-derived model of patient safety risks in primary care dentistry. This model helped to bring structure to the analysis of the 1,456 patient incident reports that were eligible for analysis out of a total of 2,000. These reports described incidents across the pre-operative (40.3%; n=587), intra-operative (56.1%; n=817) and post-operative (3.6%; n=52) clinical stages of care delivery. Further analysis showed the more frequently reported incidents were related to a) delays in treatment (333/1,456; 22.9%), b) procedural errors (220/11,456; 15.1%), c) medication-related adverse incidents (160/1,456; 11.0%), d) equipment failure (90/1,456; 6.2%) and e) errors in obtaining or processing x-rays (87/1,1456; 6.0%). Only 5.3% (77/1,456) of the incidents resulted in harmful outcomes. Of the 77 incidents that resulted in a harmful outcomes (n=77; 5.3%), around half were due to wrong tooth extractions (37/77; 48.1%) and resulted in unnecessary procedures. Three out of the 1,456 incidents (0.2%) resulted in death. Data from the scoping review and the mixed-method analysis informed a list of 42 candidate NEs. I further sought and achieved international consensus for 23 of these NEs. These were related to routine assessment, and pre-operative, intra-operative and post-operative stages of dental procedures.

Conclusions: The findings from my PhD have revealed that patient safety research in dentistry is mostly descriptive and poorly organised with various approaches to defining and measuring PSIs and their outcomes. This poor organisation of patient safety research also includes differing study designs and patient populations studied. The evidence-based conceptual framework from the systematic scoping review, and

coding frameworks from analysis of PSI reports selected from a national database, can bring structure to future work by providing a robust approach to classifying PSIs, their contributory factors and outcomes. My research findings also show that PSI reports are an important source of information that can generate important insights about patient safety in primary care dentistry. The mixed-method analysis of PSI reports showed that most incidents in primary dental care do not result in harm. PSIs that resulted in harmful outcomes more frequently occurred intra-operatively. My findings also reveal that unsafe care in dentistry is not limited to human error, but can also be ascribed to the presence of other administrative or organisational flaws that contribute to the reported incidents. Future initiatives to improve and research clinical practice should focus on improving administrative processes to reduce delays in treatment. Also, the reduction of procedural errors through the standardisation of x-rays, medication prescription and other clinical procedures is needed. Lastly, I have constructed the first comprehensive international list of NEs for primary care dentistry. I believe my findings, including the list of NEs, can provide an evidence-base which will encourage researchers to further expand the patient safety research and development agenda in dentistry, as well as encouraging decision-makers and professional bodies to translate my findings into quality improvement strategies.

Lay summary

In recent decades, there has been a lot of international attention aimed at improving the safety of hospital care, and more recently this attention has broadened to include primary medical care. In 2002, the World Health Assembly recognised the issue of inadequate patient safety as a major threat to global public health. A patient safety incident has been defined by the World Health Organization as "*an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient"*. Experiences gathered from many hospitals show that an initial key step for understanding patient safety is to gain an understanding of which incidents are the most frequent and harmful. However, despite the progress made in patient safety over the last 20 years in medicine, concerns have been raised about the limited understanding of healthcare-associated harm in the field of dentistry.

The overall aim of my thesis was to: explore and understand the types of error that have been reported from primary care dentistry, the reasons why they occurred, and their outcomes; and, identify a list of potentially serious preventable incidents that should not occur (so called 'never events').

To achieve this aim, I read the scientific literature and studied 2,000 patient safety incident reports submitted to the National Reporting and Learning System (NRLS). I used the literature review and the incident report analysis to draw up a provisional list of never events. The NRLS is a patient safety incident reporting system that was established to receive detailed reports describing incidents involving patients receiving National Health Service (NHS) funded care in England and Wales. Since 2003, this system has collected over 15 million reports with written descriptions of what happened, and why, from the perspectives of the individuals who wrote them. Around 270,000 of those reports are from primary care practices. The resulting provisional list of 'never events', after reviewing the literature and analysing patient safety incident reports, was then used to look for agreements between experts. To achieve this task, I contacted experts around the world and asked them whether they agreed on my list of 'never events'.

Studying the incident reports revealed that the main reported sources of unsafe care were related to delays in receiving treatment, procedural errors, medication-related adverse incidents, equipment failure, errors in obtaining or processing dental x-rays and wrong tooth extractions. Only a small percentage (5.3%) of the reported incidents resulted in harmful outcomes. The experts I contacted agreed on 23 never events related to events that happen before, during and after dental procedures.

My thesis has shown that the literature for the past 20 years is poorly organised, as reflected in the different research approaches used to study patient safety incidents and their outcomes. This thesis also shows that incident reporting systems, like the NRLS, are a valuable source of learning; my findings reveal that most patient safety incidents in primary dental care do not result in harm. However, those that do result in harm commonly occur during dental care delivery (intra-operatively). My findings also reveal that unsafe care in dentistry is not limited to human error, but to the presence of other administrative or organisational flaws that contribute to the reported incidents. Examples of these latter flaws include errors in managing appointments, insufficient staff members and communication errors between dental practices. Lastly, I have constructed the first comprehensive international list of NEs for primary care dentistry. I believe my findings, including the list of NEs, can help decision-makers and professional bodies to develop improvements in primary care dentistry.

Declaration

I hereby declare that this thesis was composed by me and is entirely my own work. It has not been submitted for any other degree or professional qualification.

Eduardo Ensaldo Carrasco

October 2017

Dedication

This thesis is dedicated to my parents and many friends.

I will always be grateful with my parents, Eduardo and Angelina, for giving me all the opportunities in my life.

To my brother Enrique and my sister-in-law Karla.

To my long-time friends Pavel, Eliana, Marco and Fusae.

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I dedicate this work and give special thanks to Clarissa and Latasha, for their support and bringing my feet back to ground in the most unexpected ways.

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For the third phase, I am grateful to the international panel of experts who so kindly gave of their time to support the Delphi exercise.

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Abbreviations and key terms

AEs	Adverse events
AHRQ	Agency for Healthcare Research and Quality
CQC	Care Quality Commission
FDI	International Dental Federation (FDI for Fédération Dentaire Internationale)
GA	General anaesthesia
GDC	General Dental Council
GMC	General Medical Council
ICPS	International Classification for Patient Safety
IOM	Institute of Medicine
IRS	Incident reporting system
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LA	Local anaesthesia
MeSH	Medical subheadings
NCAS	National Clinical Assessment Service
NDA	National Dental Association
NE	Never event
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NLP	Natural language processing
NM	Near miss
NPSA	National Patient Safety Agency
NRLS	National Reporting Learning System
PISA	Primary Care Patient Safety
PSI	Patient safety incident
RAND	Research and Development Corporation
UK	United Kingdom
US	United States
WAPS	World Alliance for Patient Safety
WHA	World Health Assembly
WHO	World Health Organization

Chapter 1 . Introduction

Patient safety incidents (PSIs) occur in all healthcare settings worldwide. [1-4] Since 2002, as issued in resolution 55.18, the World Health Assembly (WHA) has recognised PSIs in healthcare as a significant public health concern.[5] The resulting harm from unsafe healthcare, as seen in PSIs, is estimated to occur in one in every 10 encounters in hospitals, [2, 6-9] and in 2.0–3.0% of encounters in primary care.[10] Over the past 20 years, seminal publications in Australia,[11-13] the United States (US)[14-16] and the United Kingdom (UK),[17, 18] have encouraged healthcare organisations, researchers and policy makers around the world to focus attention on patient safety.

Currently, standard definitions of patient safety[19, 20] are available for medicine (Table 1.1), and the accumulated evidence about the extent of harm and underlying causes is in some cases beginning to be translated into interventions designed to reduce harm.[21] A global response towards patient safety in primary care began in 2012 when the World Health Organization's (WHO) Patient Safety Programme formed the Safer Primary Care Expert Working Group thereby acknowledging the importance of the issue of unsafe primary care, as well as encouraging the need for the identification of priority areas and key knowledge gaps.[3] Global research priorities for iatrogenic harm in this area were identified and reported.[22] However, this field remains in its infancy [23, 24] and this is particularly true for dentistry.[25-28]

Table 1.1 Patient safety concepts developed in medicine

Concept	Definition
Adverse event	An injury that was caused by medical management or complication instead of the underlying disease and that resulted in prolonged hospitalisation or disability at the time of discharge from medical care or both.[29]
Clinical error	The failure to carry out a planned action as intended or the application of an incorrect plan.[30]
Harm	Impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering and death[29]
Patient safety	The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.[29]
Patient safety incident	An event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.[29]
Never events	Serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented.[19]

Based on the Alma Ata Declaration,[31] the WHO defines primary healthcare as: *"...essential healthcare based on practical, scientifically sound and socially acceptable methods and technology, made universally available to individuals and families in the community through their full participation and at a cost that the community and the country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination."* [31]

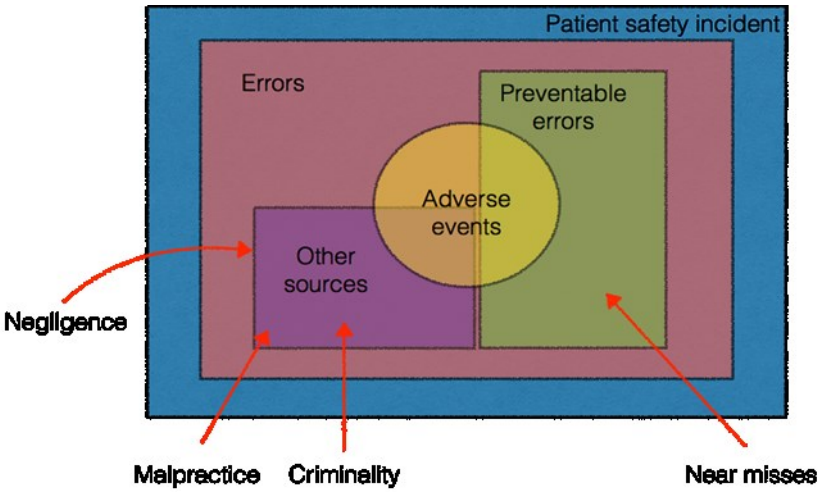
This introductory chapter provides a description of the relevant empirical evidence to contextualise my PhD degree. Initially, I explored existing terms and concepts, then I considered current frameworks and approaches to classify PSIs. After that I took a step back to consider the beginnings of the science of patient safety research, including the creation of institutions that specialised in preventive initiatives at a national and international level. Lastly, I focused on the current patient safety research gaps in primary care and summarised the progress made in the field of dentistry. This chapter also introduces definitions for the main terms I used throughout the thesis, which are summarised in Appendix 1.The goal of this chapter is to provide an overview of the conceptual framework I followed for understanding patient safety in primary care dentistry.

1.1 Terms and concepts in patient safety

The measurement of PSIs and their potential harm is a fundamental step for healthcare quality and patient safety improvement.[16, 32] The use of a standardised terminology provides a structured approach to organise PSI data so as to identify incidents and enable their categorisation. This approach can be used for standardised research methodologies, policy making and monitoring interventions designed for the reduction or prevention of PSIs.[29] However, the concepts of patient safety, error and adverse event (AE) are interrelated[33] and bring challenges for their measurement and interpretation. As shown in Figure 1.1, there is a variety of overlapping and interrelated concepts and terms used to describe PSIs in medicine. The overlap of PSIs resulting in errors, preventable and non-preventable AEs, and concepts related to malpractice and litigation has raised methodological issues for research studies attempting to compare outcomes of patient safety.[9, 32, 34] Current approaches for measuring PSIs, include a classification approach to describe contributory factors to incidents and

outcomes through risk and safety frameworks[30, 35-40] and bespoke patient safety taxonomies.[41-44] However, there is no agreement on a standardised measurement to collect PSI data and monitor/assess interventions to reduce PSIs and their outcomes,[38] as most classification systems have been developed within their respective databases from different sources of information.[45]

Figure 1.1 Overlap of terms commonly found in medical literature



In the next section, I provide an overview of patient safety as a concept and consider its relationship with quality. Then I explore the concept of error and its typology, followed by a discussion of the frameworks used in medicine for patient safety research.

1.1.1 Patient safety is a dimension of quality

The Institute of Medicine (IOM), now renamed as the National Academy of Medicine (NAM), has defined quality as "*the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge*."[32] In this context, quality and patient safety are not mutually exclusive as patient safety is a feature of quality within a healthcare system that aims to deliver services under the six dimensions of quality (Table 1.2).[32] Further, the IOM defines the aims of high quality healthcare services as being safe, effective, patient-centred, timely and efficient.[32] Therefore, improvement of patient safety is also linked to an improvement of quality that targets the measurable organisational

structure of healthcare delivery systems and their processes.[46, 47] In this context, the IOM proposed that any measurable improvements need to be compared against standards of care in line with the six dimensions of healthcare delivery, shown in Table 1.2, including patient safety.

Table 1.2 The six proposed dimensions by the IOM for healthcare improvement[32]

Domain	Definition
Safe	Avoiding injuries to patients from the care that is intended to help them
Effective	Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).
Patient-centred	Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
Timely	Reducing waits and sometimes harmful delays for both those who receive and those who give care
Efficient	Avoiding waste, including waste of equipment, supplies, ideas, and energy.
Equitable	Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

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Batalden and Davidoff (2007) defined quality improvement as "*the combined and unceasing effots of everyone – healthcare professionals, patients and their families, researches, payers, planners and educators - to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning)*".[48] However, the increased attention towards the prevention of PSIs and their outcomes has required support from other fields, such as anthropology, sociology, psychology, engineering, human factors science, and medical science. As the field of patient safety has been increasing, patient safety itself is becoming an academic discipline to support the training and education of healthcare professionals.[49]

As issued in Resolution 55.18, the WHA urged the WHO to develop standards and guidelines for the concepts and terms of quality care and patient safety for their measurement and reporting.[5] Then, seven years after this Resolution, the Conceptual Framework for the International Classification for Patient Safety (ICPS) was published

by the World Alliance for Patient Safety (WAPS).[29] In this document, patient safety is defined as *"the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum..."*.[29] Based on this Framework, a PSI was defined as an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient(s).[38] Unnecessary harm, often referred as an adverse event (AE), is defined by the WHO as "*an injury that was caused by medical management or complication instead of the underlying disease and that resulted in prolonged hospitalisation or disability at the time of discharge from medical care, or both*".[29] AEs can be classified as preventable and non-preventable. The former are of research interest for the development of evidence-based strategies for diminishing their impact. An AE is regarded as preventable whenever the event is perceived as potentially avoidable if the patient had received ordinary standards of care appropriate for the time.[29]

1.1.2 Measurement of error and harm

In 1998 in the US, reports from the IOM,[50] the Advisory Commission on Consumer Protection and Quality in the Health Care Industry[51] and the Research and Development Corporation[52] (RAND) documented quality issues relating to the over-utilisation of healthcare services, their under-utilisation and their misuse. These analyses suggested that healthcare errors can occur through human action (commission) or inaction (omission) as a consequence of cognitive failure.[41] However, PSIs and AEs are not limited to individual performance.[42, 53] According to reports from the IOM, the majority of medical errors is due to multiple failures that contribute to a single AE.[16, 32, 54] These failures related to faulty systems and processes during healthcare delivery, such as referral errors, flaws in appointments management, lack of patient follow-up, inadequate expertise or training of staff members and inadequate systems for information transfer between healthcare settings.[32]

Apart from the ICPS,[29] other frameworks for study design and interpretation in patient safety research have been developed.[36-40] The Organisational Accident Model developed by Vincent et al. (1998) for analysing risk and safety in clinical medicine,[35] and the Swiss Cheese Model of System Accidents developed by Reason,[30] differentiate errors made by people (active errors) from errors within the organisational structure of healthcare delivery (latent errors). Also, known as the 'human and systems approach',

the first seeks to identify and explain errors (unintentional errors) and procedural violations (intentional deviation of standard care) committed by the healthcare personnel, due to their mental/cognitive processes. The Swiss Cheese Model of System Accidents, however, acknowledges that human errors are common[30] and aims to identify latent flaws within the organisational structure of healthcare settings and the processes for delivery of care. These approaches have been further integrated into other frameworks such as the Yorkshire Contributory Factors Framework of PSIs in hospital settings.[55] These models are described more fully below.

1.1.3 Human error in healthcare

Before I explore the person approach to error, it is important to establish the distinction between clinical error and mistake. Clinical error, or error of planning,[54] is defined as "*the failure of applying a correct and standardised action during the process of care*".[33, 38, 41] Mistakes, or errors of execution,[54] occur when the actions proceed as planned, but the plan itself is inadequate to achieve its intended aim.[29, 41] Failure in human performance has been classified as skill-based error and rule-based and knowledge-based mistakes.[41, 56] In general, skill-based errors refer to flaws in attention, perception or memory for solving routine and / or complex tasks.[30, 41] Within skill-based errors, two types errors arise: slips and lapses (Table 1,3).

Slips are any observable, external failure in the physical execution of a plan, they generally occur as a result from deficits in attention or perception.[42] Lapses, however, occur simply by forgetting a step of a procedure, and can include errors of omission whenever there is a tendency to omit the final step(s) when the main aim of the treatment has been achieved.[56] Also needing to be taken into consideration is that both slips and lapses can also take place when there is over-attention during a procedure.[56]

Ruled-based mistakes occur when incorrect or incomplete knowledge is applied.[41, 56] Also, such mistakes can take place when an appropriate rule is applied without recognising a relative or absolute contra-indication, or when a correctly executed procedure is incorrectly chosen based, and then applied, based on past experiences, training, or a fundamental misunderstanding of the problem is applied. [41, 56] Knowledge-based mistakes occur when a problem is addressed, but the stored knowledge is inadequate to solve it.[41] In such a situation preconceptions, past

experiences and others opinions are likely to be used to solve the problem.[56] However, error and harm are not always linked,[57] patients can be injured in the absence of error, and errors may not lead to harm.[56] Errors are much more common than AEs, because many errors, even if carried through to the patient, will not turn out to be harmful.[33] This may be because: (a) luck is involved, (b) the error is not clinically significant enough to cause harm, (c) the error is caught before causing harm or (d) other mitigating factors may have prevented any potential harm.[57]

Table 1.3 Human failure types

Nature of failure	Failure type		Feature
Not intentional (Action not as planned)	Skill-based errors	Slip (Commission)	Action-based error; frequent correct actions did not proceed as planned due to flaws in attention or perception
		Lapse (Omission)	Memory-based error; frequent correct actions did not proceed as planned due to short-term memory lapse. This resulting in the omission to perform a required action
	Mistakes	Rule-based	Decision-making flaws; actions are based on remembered rules and procedures. The mistake occurs due to misapplication of a good rule or application of a bad rule
		Knowledge-based	Wrong action which is believed to be right; healthcare professionals rely on their available knowledge and experience, however, they may not have the appropriate knowledge nor experience to conduct a task or solve a problem
Deliberate (Non-compliance)	Violation	Routine	Non-compliance becomes the "norm"
		Situational	Non-compliance dictated by situation specific factors (e.g. time pressure, work load, lack of equipment); non-compliance may be the only solution to an impossible task
		Exceptional	Person attempts to solve a problem in highly unusual circumstances

Incidents which did not reach the patient are referred as 'near misses', whereas a 'no harm incident' is one in which an event reached a patient but no discernible harm resulted.[20] Both no harm incidents and near misses are considered during the initial steps for patient safety management since high detection rates are needed for the identification of unintended risk and hazards.[58] Retrospective analysis of medical records is a common method for studying past AEs, whereas prospective approaches aim to identify potential hazards by analysing the process of care.[59] For instance, reporting systems can support identifying harm incidents, no-harm incidents and near misses occurring within a healthcare delivery system.[60] Addressing the causes of near

misses can reduce the risk of actual episodes of patient harm. Therefore, strategies can be developed in order to prevent future potentially harmful events.

1.1.3.1 Violation, malpractice and negligence

The terms "violation", "malpractice" and "negligence" are commonly used in the literature. A violation is defined as a deliberate deviation from an operating procedure, standard or rule.[44] Violations often occur in poorly designed health systems to shorten processes and to save time; overtime these violations can become part of tolerated routines (see Table 1.4).[61] Also, an unnecessary procedure on a patient is a form of iatrogenic harm, and therefore the decision to undertake it must either be an error or a violation.[62] Although violations may predispose to the making of errors, only extreme deviation from the expected standard, or those that involved serious events, are reported.[63] However, some violations do not necessarily imply a disregard for safety. Situational violations can occur when circumstances arise in which a procedueal violation is unavoidable or when it is appropriate to break a rule, because doing so is thought to create less risk than the following rule (see Table 1.4).[44] When investigating errors, associated violations are relevant to evaluating the degree of moral blame.[62]

Malpractice and negligence are also terms that overlap and it is common to find they are used interchangeably. According to Studert et al. (2004) the social goals of malpractice litigations are to prevent unsafe medical practices, compensation of harm through medical negligence and to obtain corrective justice.[64] Such litigation usually involves the healthcare professional or healthcare system covering associated costs and medical bills arising from failure to meet the required standard of care. In this context, negligence referes to the failure to provide a standard level of care.[65] In the UK, the NHS Litigation Authority defines clinical negligence as "*a breach of duty of care by members of the health care professions employed by NHS bodies or by others consequent on decisions or judgements made by members of those professions acting in their professional capacity in the course of their employment, and which are admitted as negligent by the employer or are determined as such through the legal process*".[66] Within this definition, a breach of duty of care refers to an incident causing harm, damage or loss as the result of failing to provide the standard of care, whether by commission or omission, advice given or failure to advise.[36, 64, 66] If, however, the

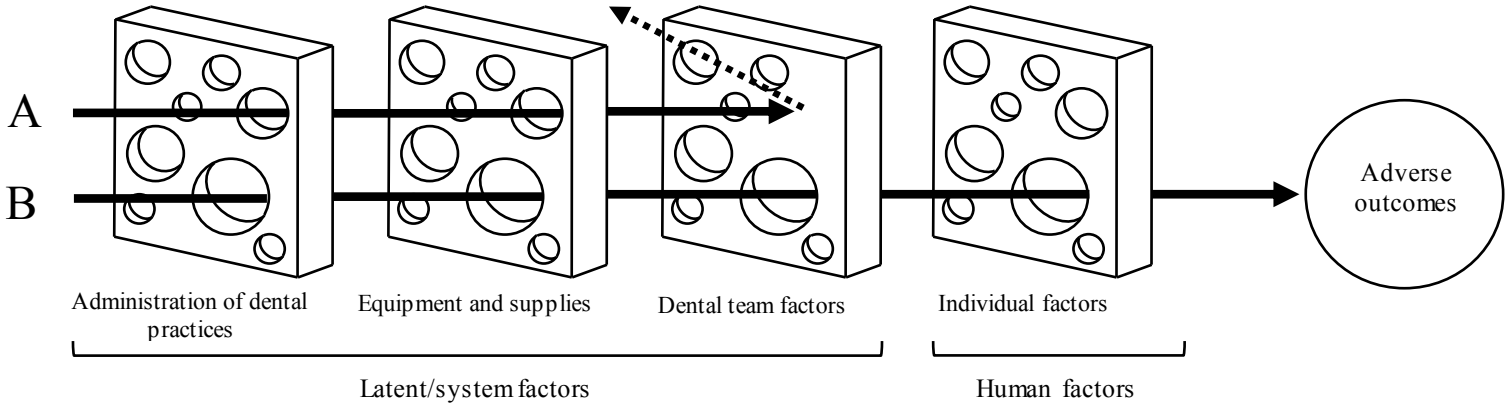
patient has not suffered any damage in terms of pain, loss of function or need for additional treatment, no harm has been caused by the negligent act.[67] However, most medical injuries are not caused by negligence.[30]

Errors should not be considered as equivalent to negligence. Errors are circumstantial, whereas negligence occurs due to true incompetence in medical practice and is generally perceived as 'failure to meet the expected standard of care'.[41] Traditionally, the standard of care usually refers to the expected behaviour of other healthcare professionals to deliver healthcare under similar circumstances and, if available, clinical practice guidelines.[64] Harm due to negligent, reckless, or criminal activity is not considered a healthcare associated harm.[56]

1.1.4 System approach to error and harm in healthcare

The system approach to error seeks to understand the conditions in which people work[30] and Reason´s Swiss Cheese Model of System Accidents has been the most referenced system-based model for patient safety research.[60] Illustrative examples of this model adapted for primary dental care are shown in Figure 1.2.

Figure 1.2 Two examples illustrating the use of Reason's Swiss Cheese Model of System Accidents to study the impact of errors in primary dental care



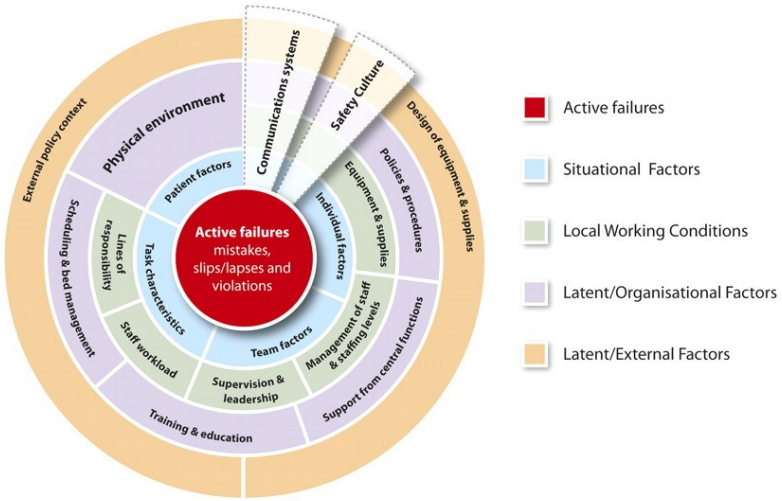
A. Poor management of appointments resulting in a busy dental clinic practice with long waiting times. **B.** Poor management of appointments resulting in a busy dental clinic practice with long waiting times. The referral letter for tooth extraction is poorly hand written.	**A.** Poor equipment maintenance. The high-speed hand piece is faulty as the engine is loose and might fall during the procedure **B.** The dental chair unit is faulty and provides intermittent and suboptimal illumination.	**A.** Trained staff realise that the hand piece is faulty. Therefore, he/she informs the dentist and replaces the hand piece with a non-faulty one. **B.** Insufficient staff members. The dentist needs to prepare all the material and equipment for all the patients.	**A.** The dentist conducts the appropriate procedure. **B.** The dentist is stressed due to the accumulating patients waiting to be treated. He/she forgets to double check the patient referral letter.	**A.** No outcome **B.** Wrong-tooth extraction

From this analysis, errors are shown to be a consequence of failures in the workplace and organisational processes at distinct levels within the healthcare system, which may include engineering, procedural, administrative as well as the absence of inefficient defensive barriers that rely on healthcare staff to intervene.[30] For example, failure of appropriate referrals, diagnostic errors, drug prescribing errors, communication problems (informal and within hierarchical structures), errors within organisational systems and technological failures have been reported as areas of concern.[21] Therefore, current patient safety research focuses mainly on health system features as well as latent risks and other factors, which that may influence the occurrence of AEs.[20]

1.1.5 The Yorkshire Contributory Factors Framework

PSIs and their AEs can be prevented through the identification of their contributory factors and the development of strategies for their prevention. According to the ICPS, a contributory factor is defined as "*a circumstance, action or influence (such as poor rostering or task allocation) which is thought to have played a part in the origin or development of an incident, or to increase the risk of an incident*."[29] Therefore, both PSIs and their outcomes are due to a series of organisational and/or human factors.[16, 32, 54] In the absence of an evidence-based list of contributory factors for their measurement and reporting in patient safety, the Humber Academic Health Science Network (AHSN) Improvement Academy developed the Yorkshire Contributory Factors Framework (see Figure 1.3).[55] This framework integrates evidence generated from secondary care into the person and system approaches to dealing with the issue of error in healthcare.[55] This framework proposes a list of contributory factors within a chronological order of organisational contributory factors (latent errors) and places active errors at the end of the chain of events. The authors also further developed the framework and, based on their systematic review[55] of the literature, identified contributory factors, in the form of latent errors from the system approach to error,[30, 60] which were broadly classified as situational factors, local working conditions, organisational factors and external factors.

Figure 1.3 Yorkshire Contributory Factors Framework



Factor	Definition
Active failures	Any failure in performance or behaviour (eg, error, mistake, violation) of the person at the 'sharp-end' (the health professional)
Communication systems	Effectiveness of the processes and systems in place for the exchange and sharing of information between staff, patients, groups, departments and services. This includes both written (eg, documentation) and verbal (eg, handover) communication systems
Equipment and supplies	Availability and functioning of equipment and supplies
External policy context	Nationally driven policies / directives that impact on the level and quality of resources available to hospitals
Design of equipment and supplies	The design of equipment and supplies to overcome physical and performance limitations
Individual factors	Characteristics of the person delivering care that may contribute in some way to active failures. Examples of such factors include inexperience, stress, personality, attitudes.
Lines of responsibility	Existence of clear lines of responsibility clarifying accountability of staff members and delineating the job role
Management of staff and staffing levels	The appropriate management and allocation of staff to ensure adequate skill mix and staffing levels for the volume of work
Patient factors	Those features of the patient that make caring for them more difficult and therefore more prone to error. These might include abnormal physiology, language difficulties, personality characteristics (eg, aggressive attitude).
Physical environment	Features of the physical environment that help or hinder safe practice. This refers to the layout of the unit, the fixtures and fittings and the level of noise, lighting, temperature etc.
Policy and procedures	The existence of formal and written guidance for the appropriate conduct of work tasks and processes. This can also include situations where procedures are available but contradictory, incomprehensible or of otherwise poor quality
Safety culture	Organisational values, beliefs, and practices surrounding the management of safety and learning from error
Scheduling and bed management	Adequate scheduling to manage patient throughput minimising delays and excessive workload
Staff workload	Level of activity and pressures on time during a shift
Supervision and leadership	The availability and quality of direct and local supervision and leadership
Support from central functions	Availability and adequacy of central services in support the functioning of wards/ units. This might include support from Information Technology and Human Resources, portering services, estates or clinically related services such as radiology, phlebotomy, pharmacy.
Task characteristics	Factors related to specific patient related tasks which may make individuals vulnerable to error
Team factors	Any factor related to the working of different professionals within a group which they may be able to change to improve patient safety
Training and education	Access to correct, timely and appropriate training both specific (eg, Task related) and general (eg, Organisation related)

(Permission for reproduction of this image is shown in Appendix 3)

1.2 Two decades of progress in secondary care

The accumulated evidence generated from secondary care over the past two decades is in some cases being translated into patient safety interventions for the prevention of unsafe healthcare delivery.[21] A full description of the historical development of patient safety worldwide is therefore beyond the scope of this thesis. The following section

will describe important milestones achieved firstly in the US, secondly, the UK and thirdly, relating to the overall international response to patient safety. Then, in the following section I will discuss the historical development of patient safety in primary care medicine and primary care dentistry.

1.2.1 United States

Initial publications can be tracked to the work from Ivan Illich published in 1975.[68, 69] In his work, Illich argued about the negative impact of modern medicine on society due to ineffective and unsafe medical care (clinical iatrogenesis), medicalisation of life (social iatrogenesis) and the destruction of traditional approaches to deal with sickness and death (cultural iatrogenesis).[69] Later, the Medical Insurance Feasibility Study[70] (1977) reported 4.6% of cases of disability were due to healthcare mismanagement in hospitals in California. Fourteen years later, Brennan et al. (1991) published the Harvard Malpractice Study[14] which reported incidence rates of 3.7 for AEs and 1.0 for negligent AEs per every 100 hospitalisations in New York. They also reported that 58.0% of the reported AEs were preventable.[14] Later studies by Thomas et al. (1999, 2000) in hospitals from Colorado and Utah[71, 72] employed a similar methodology to that used by the Harvard Malpractice Study and estimated an incidence rate of 2.9 of AEs for every 100 hospitalisations.[72] The Utah study reported surgical complications, adverse drug events and delayed/incorrect diagnosis and / or treatment as the most expensive types of AEs.[71]

In 1998, the IOM[50] highlighted evidence from the Advisory Commission on Consumer Protection and Quality in the Health Care Industry[51] and RAND Corporation[52] and raised awareness about the over-utilisation and under-utilisation of healthcare services as well as practice-related errors. From here, the IOM released the report *To err is human* to bring national attention to patient safety in the US.[16] In this report, the findings from the studies conducted in Colorado and Utah[71, 72] and the findings from the Harvard Malpractice Study[14] were used to estimate the burden of medical errors in hospitals across the US. The report estimated between 40,000 to 98,000 annual deaths were due to medical error, and that over 1 million patients were injured as a result of the same cause; they estimated an annual cost of preventable AEs between $17 billion and $29 billion.[16] After this, the IOM followed by issuing recommendations for the

strategic redesign of the healthcare system.[32] The recommendations included the development and implementation of a national reporting system. Formal nation-wide responses from the US started with the establishment of the Agency for Health Care Policy and Research in the US (1989) which was later renamed as the Agency for Healthcare Research and Quality (AHRQ).[73] Other national bodies that were funded in response to patient safety concerns are the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the non-profit organisation known as the Institute for Healthcare Improvement (IHI).

1.2.2 United Kingdom

The focus on patient safety in the UK started in 1999 with the release of a consultation paper issued by the Department of Health.[74] This document provided insights into the poor processes for the timely identification, prevention and management of poor clinical performance. The paper also highlighted the need for exploring potential contributory factors at an individual level, as well as within the healthcare system that might affect clinical performance. Then, in the same year, the NHS required group of experts to understand the extent of PSIs and their outcomes, and to propose approaches for their identification, collection and analysis. This challenge resulted in the report *An Organisation with a Memory*[17] published in 2000 by the Department of Health. This document firstly provided an overview of the problem and, secondly, set out a plan for the development and implementation of a national and local system for the identification of PSIs and their outcomes. Due to the scarcity of reliable information, the group of experts commissioned by the England Department of Health extrapolated the findings from the Harvard Malpractice study[14] and the Quality in Australian Health Care study[11] and obtained broad estimates between 3,000 and 1.4 million of AEs that occurred in NHS hospitals were offered.[17] Also, extrapolated from a small-scale pilot study conducted by Vincent et al.,[18] the estimated annual cost of AEs to the NHS was around £2 billion.[17] The report recommended the development of a unified national mechanism to report, analyse, monitor and learn from PSIs in the NHS.

Another important report in 2001 was the public inquiry into children's heart surgery at the Bristol Royal Infirmary.[75] The aim of this inquiry was to investigate the deaths of 29 babies who underwent heart surgery at Bristol Royal Infirmary between 1984

and 1995. In this report, poor performance and errors of the healthcare professionals were due to latent organisational errors within the healthcare system. Overall, these errors were related to the low priority given to vulnerable children, poor standards for quality care, a culture of secrecy for disclosing the performance of doctors and poor approaches to ensure patient safety. In the same year, following the report *An Organisation with a Memory*,[17] the Department of Health published the report *Building a Safer NHS for Patients*.[76] This report proposed an integrated approach through the creation of the National Reporting Learning System (NRLS) and the establishment of the National Patient Safety Agency (NPSA) in England and Wales. Other formal national responses towards patient safety were the creation of the National Clinical Assessment Authority, whose functions were later transferred to the National Clinical Assessment Service (NCAS), and the Commission for Health Improvement which is now operated NHS Litigation Authority.[77]

1.2.2.1 Policies and strategic developments for improving patient safety

The field of patient safety has now moved on from developing standard definitions, and describing the extent of harm to the underlying causes and, more recently, interventions designed to reduce harm.[23] However, as a dimension of quality, patient safety in healthcare must be assured at a national or regional level through policies and strategic developments.[47] In the UK, after the publication of *An organisation with a memory*,[17] initiatives following this report included the establishment of the NPSA in England and Wales, the NCAS[77] and the Commission for Health Improvement, now replaced by the Care Quality Commission (CQC) since 2009.[78] However, through the years, their functions have been transferred to different regulatory bodies. In 2002, the roles of the NPSA were transferred to the NHS Commissioning Board Special Health Authority, which later was transferred to NHS England in 2013. From 2016, patient safety is being managed by NHS Improvement. A timeline of events, policies and strategic developments is shown in Table 1.4.

Table 1.4 Timeline of relevant events, policies and strategic developments towards the improvement of patient safety within the United Kingdom

Year	Action
1999	• Establishment of the Commission for Health
1999	• Establishment of the National Institute for Health and Care Excellence
2000	• Publication of *An Organisation with a Memory* • Publication of *Building a Safer NHS for Patients*
2001	• Foundation of the National Patient Safety Agency for England and Wales
2002	• Roles of the NPSA transferred to the NHS Commissioning Board Special Authority
2003	• Establishment of the National Reporting Learning System
2004	• Launch of the Health Foundation's Safer Patients Initiative
2004	• Publication of 7 Steps for Patient Safety
2004	• The Commission for Health is replaced by the Healthcare Commission
2005	• The National Institute for Health and Care Excellence merged with the Health Development Agency and changed its name to the National Institute for Health and Clinical Excellence (NICE)
2005	• Introduction of a dedicated patient safety improvement programme that precedes the Scottish National Patient Safety Programme
2008	• Patient Safety First campaign launched in England
2008	• Due to the international interest, UK's NICE founded NICE International. They offer advice to governments and governmental agencies overseas on building capacity for assessing and interpreting evidence to inform health policy and on designing and using methods and processes to apply this capacity to their local country setting
2009	• Introduction of the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation • Introduction of the Never Events Policy and Framework
2009	• The Healthcare Commission is replaced by the Care Quality Commission (independent regulator of health and adult social care in England)
2009	• The first healthcare system worldwide to introduce the mandatory use of the World Health Organisation's Surgical Safety Checklist
2012	• Commissioning Board set up a taskforce to assess surgical never events and issue recommendation towards their eradication from NHS surgery
2012	• The General Medical Council released the guide *Raising and acting on concerns about patient safety*
2013	• Evidence Based Networks was founded to provide help improve healthcare through better use of evidence, best practice, information and communication
2013	• Roles of the Commissioning Board Special Authority are transferred to NHS England
2013	• The National Institute for Health and Clinical Excellence took on responsibility for developing evidence-based guidelines and recommendations for quality standard in England, also known as NICE guidelines. NICE guidance is also provided to Wales, Scotland and Northern Ireland.
2013	• The National Framework for Reporting and Learning from Serious Incidents Requiring Investigation is replaced by the Serious Incident Framework

Year	Action
2014	• The national patient safety campaign "Sign up to Safety" is launched
2014	• Publication of the Surgical Never Events Taskforce report
2014	• Establishment of 15 Patient Safety Collaboratives led by England's Academic Health Sciences Networks
2015	• Introduction of the Revised Serious Incident Framework • Introduction of the Revised Never Events Policy and Framework
2015	• Introduction of National Safety Standards for Invasive Procedures
2016	• Roles of NHS England are transferred to NHS Improvement

Professional bodies in the UK have defined the standards for healthcare delivery through the development of healthcare guidelines, the establishment of patient safety competencies, standards for Information Technologies (IT) systems and implementation of quality-focused infrastructures.[79] An example of these standards is the practice guidelines from the National Institute for Health and Care Excellence (known as the NICE guidelines).[80] Initially established in 1999 for England, NICE currently provides guidance to Wales, Scotland and Northern Ireland as well. Since 2008, due to global interest, NICE International was founded.[81] National Safety Standards for Invasive Procedures,[82] are also available, as are the standards for medical competence across UK's Royal Colleges. Patient safety standards for IT employed with clinical risk management systems developed by the Health and Social Care Information Centre,[83] is now known as NHS Digital.

The development and introduction of policies is another approach taken to address patient safety at a national level. Examples of these initiatives include the introduction, in 2009, of the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation,[84] and the Never Events Policy and Framework.[85] Since then, these have been updated and renamed as the Revised Serious Incident Framework[86] and the Revised Never Events Policy Framework.[87] Serious incidents are defined as "*events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response.*"[86] A subset of these incidents is comprised of NEs, being defined "*as serious, largely preventable PSIs that should not occur if the available preventive measures are implemented*".[19] The supporting criteria for this definition in shown in Table 1.5.

Table 1.5 Never event criteria developed by the National Patient Safety Agency[19]

- It is wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers (preventability)
- It has the potential to cause serious patient harm or death. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorised as a never event (seriousness)
- There is evidence of its occurrence in the past, and a risk of recurrence remains (past and future risk)
- It is easily recognised and can be clearly defined (recognisable)

This definition and corresponding criteria are also supported by a list of NEs for hospital settings developed in England by the NPSA in 2009 and further revised by the UK Department of Health in 2015.[19] Due to their clear potential for severe harm,[87, 88] national guidance and national safety recommendations encourage the reporting of NEs.[87, 88] In England, such policies enable Clinical Commissioning Groups (CCG) to recover healthcare costs when a procedure or treatment results in a NE.[89] NEs are collected and monitored in patient safety incident reporting systems overseen by the NHS Improvement's Patient Safety Domain.[90]

1.2.2.2 Incident reporting systems

According to the WHO, the fundamental role of incident reporting systems is "*to enhance patient safety by learning from failures of the health care system*".[91] To achieve this, policymakers need to retrieve evidence about performance and outcomes.[47] Useful lessons can be obtained from PSIs, including near misses and NEs. Over the past 20 years, PSI reporting systems been developed and implemented in the USA,[92] Canada,[93] Australia[94] and Europe.[95]

Incident reporting systems may be compulsory or voluntary.[38, 95] National-level data from these systems can allow the identification of patient safety priorities for intervention, unsuspected hazards or reports of the malfunction of devices or equipment used for healthcare delivery.[38] In the UK, the NRLS for NHS practices in England and Wales was established.[76] The NRLS is a voluntary, national reporting system created in 2003. However, all serious incidents (including NEs) are mandatory to report, and since 2010 it is also mandatory to report any incidents that resulted in

severe patient harm or death. The NRLS is one of the most comprehensive reporting systems in the world, having collected over 10 million incident reports since its creation.[96, 97] It provides a clear focus on patient safety within the overall NHS quality programme through a systematic structure that enables the identification, recording, reporting and analysis of PSIs (including near misses) and their outcomes.

1.2.2.3 Professional compliance with regulations

To make the patient-safety-oriented regulations/policies work, healthcare professionals, organisations and professional teams are all expected to provide the highest possible standard of care while considering the needs of the patients and their communities.[47] To achieve this aim, their performance can be regulated by either strengthening current healthcare regulatory bodies or developing new ones to deal with poor levels of clinical performance. Examples of these regulatory bodies within the UK are the Professionals' Standards Authority[98] which oversees independent regulatory agencies such as the General Medical Council (GMC)[99] and the General Dental Council (GDC).[100] These regulatory agencies, in their areas of interest, set the standards of competence and conduct that healthcare professionals must meet to obtain and maintain their registration and fitness to practise. Additional functions include reviewing the content and quality of education and training courses and conducting enquiries about complaints. For example, the GDC has the responsibility to assure the quality of education and training for all UK programmes[100] in accordance with the GDC's *Standards for Education*.[101] These standards cover the areas of i) patient protection, ii) quality evaluation and review and iii) student assessment, [101] which any education or training programmes are required to meet in order to be accepted for registration. For established approved programmes, the GDC conducts periodical inspections, every five years, to ensure the *Standards for Education*[101] are maintained. Other measures to tackle patient safety are the CQC[78] and the NCAS to address the poor performance from doctors, dentists and pharmacists.[102]

However, guidance is also needed and the guide *The Seven Steps for Patient Safety* developed by the former NPSA is an example of a checklist to guide healthcare professionals to plan their activities and measure their patient safety performance.[103] Also, clinical governance is the way in which local services can assure, and seek ways

to improve the quality of their services by putting in place the systems, networks and staff competencies necessary to do so (Table 1.6).[104] Clinical governance is a systematic approach to maintaining and improving the quality of patient care within a health system; for example the NHS Trust. Another strategy learned from the human factors research undertaken in hospital-based studies is to reduce among the healthcare staff, their reliance on memory when they provide care.[105] Apart from standardisation of procedures, development and compliance of protocols, the implementation of patient safety checklists has been developed[106] to reduce flaws that may depend on memory, attention or perception from healthcare staff.[105]

Table 1.6 Areas of improvement within the framework of clinical governance

Areas of clinical governance
Risk management
Clinical audit
Education, training and continuing professional development
Evidence-based care and effectiveness
Patient and carer experience and involvement
Staffing and staff management

1.2.2.4 Education and training

The major sources of patient safety education in the UK and most developed countries have been developed by patient safety initiatives. In the UK, the *Safer Patients Initiative* was the first major improvement programme that addressed patient safety from 2004 to 2008. The report, *Safer Patients Initiative: Lessons from the first major improvement programme addressing patient safety in the UK*, provided an important source of organisational learning as it identified poor data management, poor reorganisation and executive change, and poor staff engagement as the main barriers to progress.[107] Also, from 2008 to 2010, the Patient Safety First campaign focused on improving patient safety culture within the NHS[108] providing educational tools for leadership building and intervention in patient safety,[109] and the application of human factors in healthcare.[110] The NHS Institute's Leading Improvement in Patient Safety programme[111] was also developed to support NHS Trusts to develop patient safety improvement strategies. Other national approaches in the UK were also developed and implemented. In Wales, between 2008 and 2009 the *1000 Lives Campaign* was introduced, to be followed by the *1000 Lives Plus* campaign. The latter campaign was

further expanded in order to introduce a national programme to improve the quality of healthcare in Wales. It is now known as *1000 Lives Improvement*.[112]

An example in Scotland to foster patient safety is the Scottish Patient Safety Programme, which was introduced in 2008, supported by NHS Scotland Quality Improvement, and it is considered the first Patient Safety Programme to be introduced anywhere in the world.[113] More recently (March 2016), Health Education England, the regulatory body responsible for all the healthcare workforce, established the independent Commission on Education and Training for Patient Safety.[114] The Commission issued recommendations for the education and training for patient safety within the NHS[115] and is broadly concern with: 1) the creation of a culture of shared learning, 2) the patient at the centre of education and training,3) lifelong learning and 4) delivering education and training for patient safety.[115] In the report *First, do no harm*, the Medical Schools Council and the GMC show examples of the integration of patient safety within teaching initiatives across undergraduate medical programmes in the UK.[116] These examples range from the introduction of patient-safety-oriented programmes, the practical use of the WHO surgical safety checklist,[106] the sciences of human and system errors in healthcare and learning about infection control practices.

1.3 International response towards the prevention of patient safety incidents in secondary care

Patient safety assurance is a shared goal between healthcare systems around the world that should not be limited to high-income economies, but should also include low- and middle-income economies.[117] The publications such as *To err is human*, *An Organisation with a Memory* and the Quality in Australian Health Care Sudy[11] attracted international attention as the two works showed similar findings.

In early 2002, the Executive Board of the WHO recommended Resolution WHA55.18 to bring international attention to patient safety. In the same year, the Resolution was passed by the Fifty-fifth WHA which recognised AEs as a public health concern.[5] This document urged WHO member states to promote patient safety as a fundamental principle of all health systems and requested the development of global norms, standards and guidelines for quality of care and patient safety.[5] As a result, in 2004, the World Alliance for Patient Safety (WAPS) was formed.[118] Later, in 2009, the

WAPS was renamed the WHO's Patient Safety Programme and issued recommendations towards the understanding of the epidemiology of AEs with particular interest in the processes leading to them.[1] In the same year, in 2009, the WHO's the Patient Safety Education Programme was also established.[119]

Following the adoption of Resolution WHA55.18,[5] the WHO developed a set of 20 global priorities for research.[9, 120] Further progress made by the WHO includes: 1) the publication of their Conceptual Framework for the International Classification for Patient Safety[29] in order to foster standardised reporting of incidents; 2) the WHO Guidelines for Adverse Event Reporting and Learning Systems to promote continuous learning from patient safety incident reports;[91] and 3) the Patient Safety Curriculum Guides for Medical schools[121] in 2009 and, in 2012, the multi-professional edition of the Guide[122] was produced in order to help healthcare leaders, schools and students to integrate and promote patient safety knowledge and skills within their curricula. These Guides were based on the National Patient Safety Education Framework developed by the Australian Council for Safety and Quality in Health Care.[123] The WHO has also made materials from workshops available to foster learning from errors[124] and, in 2014, drafted a framework for the core leadership competencies required to oversee and manage patient safety and quality of healthcare.[125]

Despite the progress made in hospital care settings, it is clear that work still needs to be done; particularly in developing countries and countries with their economies in transition.[2, 126] The WAPS reported that the global evidence of patient safety is produced mainly in developed economies and is distributed into three areas of work: 1) the organisational structure of healthcare delivery; 2) the processes for delivery of care and 3) the consequences (e.g. AEs).[2] Also, Rodriguez et al.[126] used bibliometric data, mapping global patient safety research activity from 2000 to 2010 into research focused mainly on the measurement and reporting of incidents (42.0%) and much less focused on the identification and understanding of PSI contributory factors (31.0%) or the implementation of solutions at an organisational or national level (19.0%). More recently, Schreiber et al.[127] reviewed the global patient safety literature over a period of 50 years (1960-2014) and found that of 4079 articles, most published studies came

from the US (n=2068), UK (n=556), Canada (n=221), Germany (n=148), Australia (n=145) and the Netherlands (n=121).

1.4 International call to action to patient safety in primary care

Whilst progress has been made in secondary care, by contrast there has been very little progress in this field in primary care.[23, 24, 128] It was not until 2001 when research, action and leadership for patient safety in primary care were fostered.[129] In the same year, the AHRQ presented an Agenda for Research in primary patient safety in the US.[130] Also in the early 2000s, Australia, Canada, England, the Netherlands, New Zealand and the US formed the LINNAEUS collaboration and proposed a classification system for patient safety in primary care.[131] Then, half a decade later in 2008, the LINNEAUS Euro-PC collaboration was funded by the European Union Framework 7 Programme. This European Union initiative proposed their own classification system[132] and issued recommendations for research in primary care within the Union.[133] More recently, in 2015 the Primary Care Patient Safety (PISA) Classification System[134] was proposed to identify the most frequent and most harmful PSIs, and relevant contributory issues, occurring within general practice. Evidence has accumulated since the 1980s from a variety of study designs, with an estimated median frequency of 2-3 incidents per 100 consultations/patient records.[10]

A global response towards patient safety in primary care began in 2012, when the WHO's Patient Safety Programme formed the Safer Primary Care Expert Working Group and acknowledged: 1) the importance of dealing with unsafe primary care, 2) the integration of baseline measurements with quality improvement in low- and middle-income settings, 3) a need for the identification of priority areas and key knowledge gaps, 4) recognition of the need for increased knowledge together with practical proposals to bridge major knowledge gaps, and 5) suggestions for a roadmap for action.[3]

Global research priorities for iatrogenic harm in primary care were reported.[22] These priorities include the improvement of data collection methods and improved taxonomies for learning about PSIs in primary care.[22] Moreover, further PSI-research priorities were identified and include improvements in communication among

healthcare professionals, staff teamwork, laboratory and diagnostic imaging investigations, data management, transitions between different care settings, and medical records.[22]

1.5 Patient safety in primary care dentistry

Having discussed the developments of patient safety in secondary care and primary care in medicine, I will now proceed to explore the field of patient safety in dentistry. The WHO's emerging agenda for "Safer Primary Care" [3] has advocated the need for a better understanding of patient safety in primary care,[23, 24] which includes dentistry.[25-28] The reason behind the infufficient attention to patient safety in primary care dentistry may be explained by a generalised assumption that this sector is safer than the hospital sector.[135] Dentistry is often approached by the public from a business-model perspective instead of a healthcare profession, as the demand for aesthetic dentistry increases.[136, 137] Moreover, dentistry keeps a balance between patient demand (often aesthetic) and professional standards of practice.[136] Nonetheless, injuries with varying degrees of harm can occur among dental patients.[138-140]

Research into the conceptual understanding of patient safety and the epidemiological data of PSIs is needed.[26] The National Dental Associations, surveyed by the International Dental Federation (FDI for Fédération Dentaire Internationale), has called for information and knowledge about patient safety in primary care dentistry, in terms of what lessons can be learnt from PSIs, drug-related PSIs, as well as the ethical and legal aspects of patient safety.[27] Also, the Council of European Dentists has recommended the introduction of incident reporting systems.[141] Unfortunately, only two studies have assessed reports from this resource.[142, 143] Firstly, Thusu et al. analysed 2,012 patient incident reports from which they reported injuries, medical emergencies, inhalation and ingestion of foreign objects, adverse reactions and wrong-tooth extractions as the main areas of concern within a period of one year.[142] Later, Renton and Sabbah reviewed the same data from 2005 and 2014 to report the frequency of serious incidents and never events related to dentistry.[143]

NEs are also a promising area for research in dentistry.[144] However, wrong-tooth extractions are currently the only specifically defined NE related to dentistry that has

been included in the NE list used in the English NHS[19] an incident which accounts for around 120 reported cases per year.[90, 143] Little is known about other potential NEs that can occur in dentistry. As a result, no formal list has been developed for primary care dentistry, and no systematic attempts have been made to identify and propose NEs for international use. Black and Bowie took an initial step in proposing a list of NEs for primary care dentistry.[145] However, although promising, the authors acknowledged the study required a more systematic approach to review the literature and identify other potentially missed NEs; also needed was a greater diversity of participants representative of the dental practitioner population.[145]

Guidelines and standards of care to ensure high quality and safe dental procedures are available from the GDC.[146] Such standards are supported by the development of a revalidation scheme to ensure practising dentists within the UK remain fit to practice.[147] However, the historical development of dentistry as a profession from an experience-based to evidence-based practice has been a challenge for measuring the quality of care delivery due to the broad variability of dental treatments and scarcity of clear evidence-based guidelines.[148] Evidence-based dentistry provides professionals the opportunity to apply relevant empirical research findings to primary dental care.[149] However, when compared with medicine, the evidence-based dentistry is its early development.[148] Limitations include the poor quality of available evidence used to develop evidence-based guidelines and the insufficient compliance with them amongst practitioners.[149, 150]

Bailey et al. (2015) systematically reviewed the literature for current patient safety strategies in dentistry.[26] They found that the efficacy of electronic tools, reporting systems and trigger tools in dentistry is unclear as they have not been tested. Only surgical safety checklists showed their efficacy to reduce or minimise AEs.[26] Nevertheless, primary dental care professionals need to be cognisant of the most reliable expected standards of care even when clinical guidelines or tools for the prevention of PSIs are not available. The GDC's Standards for the Dental Team[146] mandate all dental team members to: 1) provide good quality care based on current evidence and authoritative guidance, 2) work within their existing knowledge, skills and professional competencies and 3) continuously update and develop their

professional knowledge and skills throughout your working life. [146] These standards should therefore, where possible be followed by practitioners.

1.6 Chapter summary

In summary, the literature review presented within this chapter indicates that there is a need to understand the field of patient safety in primary care dentistry. To contextualise my PhD, I reviewed the relevant literature in patient safety research in primary and secondary care. Then, I presented a discussion of the terms and concepts used in secondary care. For this PhD, to bring an overall structure of the studies, I decided to use the WHO ICPS classification as my preferred terminology for PSIs, AEs and contributory factors. I used the definition of NE as offered in the Revised Never Events Policy and Framework.[87] The complete list of preferred terminologies and definitions is shown in the Appendix 1 of this thesis. I also discussed the human- and system-based frameworks to measure error and harm and their subsequent integration into Yorkshire Contributory Factors Framework.[55] These frameworks aided me throughout my PhD degree to bring conceptual structure to my methods and interpretation of the results.

I believe the work derived from this thesis to be important in light of the patient safety agenda within the *Safer Primary Care* report[3] developed by the WHO, particularly in providing a better understanding of reported PSIs and AEs, and identifying priority areas and key knowledge gaps. This report also demands the recognition of the importance of unsafe primary care, including dentistry. I also believe this work can inform further short- and medium-term research strategies.

I will now describe in detail, in the following chapters, the aims, objectives and methods employed for each phase of my PhD on Population Health Sciences.

Chapter 2 . Aims, objectives and overview of methods

2.1 Introduction

As discussed in Chapter 1, it appears that primary care dentistry has not received appropriate attention to understand the role of patient safety within this discipline. Concerns have been raised about the limited understanding of the concepts and terminology relating to patient safety,[26] along with the main risks to unsafe dental care delivery,[151] including NEs.[144] Therefore, this PhD was designed to understand the safety risks and priorities for patient safety in primary care dentistry. To achieve this understanding, I structured my PhD according to the aims and objectives listed in sections 2.2 and 2.3.

2.2 Aims

The overall aim of my PhD was to examine patient safety, its concepts, as well as the processes of error and healthcare associated harm and how understanding these events can be used to assess and analyse PSIs and their outcomes in primary care dentistry.

In more detail, I aimed to:

- Obtain a comprehensive overview of relevant conceptual work and empirical evidence of PSIs and AEs in primary care dentistry;
- Understand the nature of PSI reports from dentistry in the NRLS and provide insights into the nature and type of PSIs and their outcomes;
- Identify contributory factors to PSIs;
- Identify the most frequent and severe threats to patient safety in primary care dentistry, and with the greatest opportunity for improvement; and,
- Establish an expert consensus on NEs for primary care dentistry in order to reduce or minimise serious harm

2.3 Objectives

My specific objectives of the PhD were to:

- Conduct a systematic scoping review of the empirical literature in order to understand the global extent, range and nature of relevant theoretical literature and empirical research activity relating to the types and frequencies of PSIs and AEs arising from primary care dentistry;
- Characterise the reports submitted to the NRLS into categories and subcategories of PSIs, contributory factors, outcomes and severity of harm;
- Identify patterns in chronological order of multiple incidents with their related contributory factors;
- Identify which PSIs can be considered as potential NEs; and,
- Establish an international expert-informed consensus-based list of NEs for primary care dentistry.

2.4 Overview of the methodological approach

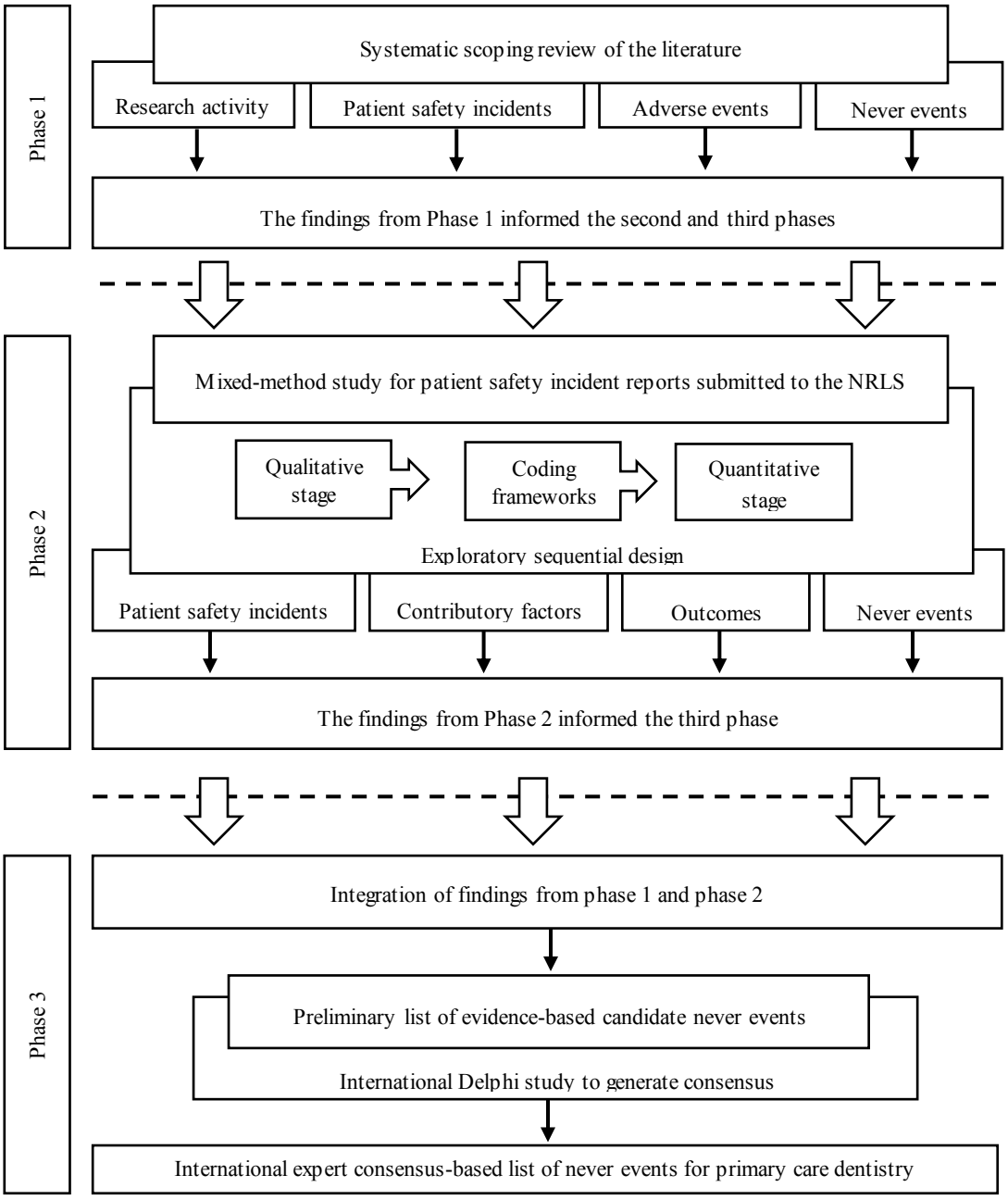
This thesis was undertaken in three complementary, sequential phases. As Figure 2.1, shows, I began the first phase with a systematic scoping review of the literature. I produced a comprehensive account of current relevant empirical research activity and theoretical literature in primary care dentistry, particularly on PSIs, AEs and NEs. The results of this phase were also used to inform the second and third phases.

For the second phase of my thesis, I employed a mixed-methods exploratory sequential design[152, 153] to interrogate free-text descriptions of PSIs submitted to the NRLS, so as to understand PSIs, their contributory factors and outcomes reported by healthcare professionals from the field of primary care dentistry.

After the review of the literature and analysis of the NRLS database, the third phase consisted of a modified Delphi exercise to develop a list of 'never events'. The data

obtained from both the literature review and the NRLS database served as the basis for defining and developing the questionnaire used in the Delphi method.

Figure 2.1 Structure of the PhD



2.5 Chapter summary

This chapter has provided a description of the aims, objectives and the overall structure of my PhD. As shown in Figure 2.1, the results of the first and second phases informed the subsequent remaining phase(s) of my PhD. I will now proceed through describing

the systematic review, to explore the global extent of the current evidence base and knowledge gaps in patient safety research in primary care dentistry.

Chapter 3 . Patient safety incidents in primary dental care: a systematic scoping review

3.1 Introduction

Chapter 1 has outlined the need for exploring the field of patient safety in primary care dentistry. National dental associations have called for more information about unsafe dental care and have highlighted the need to learn lessons from dental errors.[27] As Pemberton outlined,[151] the identification of the main risks to patient safety is a necessary step to understanding the magnitude of unsafe care in dentistry. However, no concerted efforts have been made to systematically review the current empirical evidence for understanding patient safety in dentistry. This chapter describes the systematic approach I followed to understand the globally generated theoretical literature and empirical research activity surrounding types and frequencies of PSIs and AEs in primary care dentistry.

3.2 Aim

To obtain a comprehensive overview of relevant conceptual work and empirical evidence of PSIs and AEs in primary care dentistry.

3.3 Objective

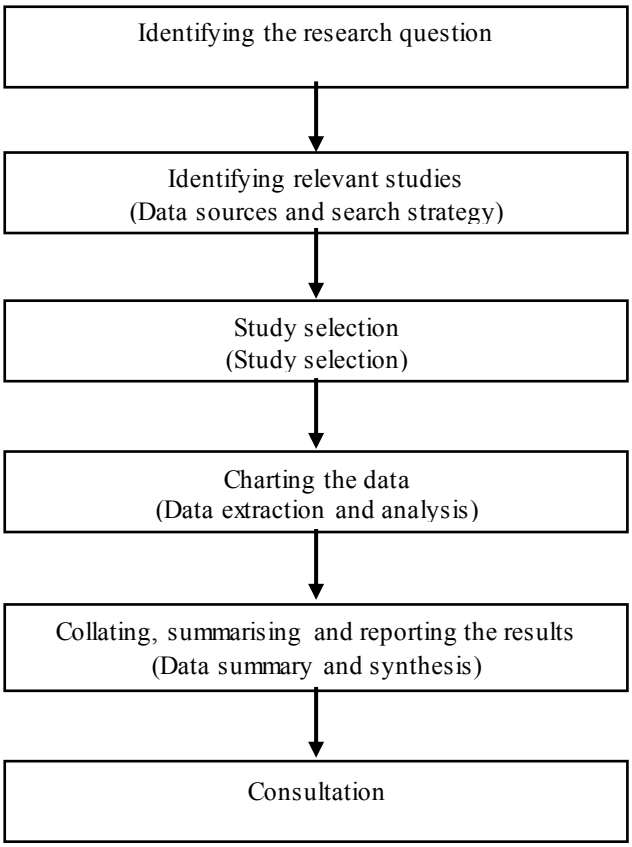
I sought to undertake a systematic scoping review of the empirical literature to understand the globally generated range and nature of relevant empirical research activity and theoretical literature in regard to the types and frequencies of PSIs and AEs arising from primary care dentistry.

3.4 Methods

Due to the anticipated broad nature and heterogeneity of studies to screen, I decided to conduct a systematic scoping review.[154, 155] In contrast to systematic reviews, this technique is recommended to map broad topics with a diverse variety of study designs and methodologies, particularly when the body of evidence is still emerging. For this thesis, my methodological approach was adapted from the framework developed by Levac et. al.[155] (see Figure 3.1) to facilitate the identification of relevant studies, study

selection and charting the data. However, I also drew on Cochrane's systematic review principles for the literature search and selection criteria.[156]

Figure 3.1 Framework proposed by Leval et al. for conducting systematic scoping reviews



The reporting of the results followed, where appropriate for a scoping review, by employing the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) checklist.[157]

3.4.1 Data sources and search strategy

I decided to narrow my search strategy to MEDLINE and EMBASE as these as these databases are the main sources for dentistry-related research publications (see Appendix 4). My decision to focus on these two databases and to not include other databases such as Web of Science and Scopus was supported by: 1) an initial exploration of these databases, which revealed insufficient number of dentistry-related articles, and 2) the feedback received from these initial findings by a librarian (Marshall Dozier) at the Main Library from The University of Edinburgh. The same

librarian, aided me to develop a search strategy with a set of established medical subheadings (MeSH) and free-text terms (see Appendix 5). The screening period accessed material that ranged from January 1994 to January 2015. Due to its relevance within the medical field, the year of publication of *Error in Medicine*[158] in 1994 was considered to be an appropriate start date. Due to time required to screen publications over a period of 20 years, I decided to use a *snowball* approach instead of hand searching journals to identify potentially relevant publications missed in the search strategy. The *snowball* approach consisted in screening the reference lists of all the eligible full-text articles for the review.[159] Within these, two reviewers (EEC & MF) screened and assessed whether titles and abstracts were for further inclusion in the review.

3.4.1.1 Eligibility criteria

I included studies that reported any type of incident that could have resulted or actually did result in unnecessary harm from to primary dental care. Primary dental care settings included all individual practices, community practices, private practices and hospital outpatient clinics.[160] Opinion studies, forensic studies, disease risk management, as well as recommendations for antibiotic prophylaxis, treating patients with pre-existing medical conditions or occupational hazards were also discarded. Articles that reported PSIs or AEs but lacked information about their frequency were eliminated. The detailed criteria for inclusion and exclusion of the included studies is shown in Table 3.1.

Table 3.1 Inclusion and exclusion criteria for the included articles

Inclusion	Exclusion
Any study that reported: • Any incident that could have resulted in unnecessary harm • Any incident that resulted in unnecessary harm	Recommendations for: • Disease risk management • Antibiotic prophylaxis • Treatment of patients with pre-existing medical conditions
Primary dental care settings: • Individual practices • Community practices • Private practices • Hospital outpatient clinics	Other: • Opinion studies • Forensic studies • Disease risk management articles

3.4.1.2 Types of included studies

The following study designs were considered for inclusion:

- Theoretical studies (e.g. investigations into human and system errors in dentistry);
- Systematic reviews;
- Experimental studies (e.g. randomised controlled trials, controlled clinical trials, controlled before and after studies, interrupted time series);
- Epidemiological studies (e.g. descriptive and analytical studies); and,
- Qualitative studies (e.g. ethnographic, interviews, focus groups).

3.4.1.3 Outcome measures

The primary outcomes were PSIs and AEs as defined in Table 1.1. in Chapter 1. Furthermore, potential candidate issues that could meet the criteria for NEs (Table 1.5) were considered according to the definition provided by England and Wales' former NPSA.[19]

3.4.2 Study selection

Two reviewers (EEC and MF) independently reviewed the articles for inclusion. To achieve this, I recruited and trained a PhD student from the Centre for Population Health Sciences as the second reviewer (MF). As MF did not have a background in dentistry, his training included an overall introduction to the discipline, its treatments and related terminology. Additional training included an introduction to patient safety, its terminology (Table 1.2) and examples applicable to dentistry (Figure 1.2). The citations were imported into EndNote 6 software[161] where all duplicates were deleted. Initially, only the title and abstracts were screened. Then, full-text copies were obtained and assessed for eligibility. If not available, authors were contacted and a copy was requested. In case of a disagreement, a third reviewer (Aziz Sheikh) was consulted.

3.5 Data extraction and analysis

Data were extracted into a customised form using Microsoft Excel 2011 software.[162] The main categories for data extraction (Table 3.1) were agreed by the reviewers. The full data extraction form is shown in Appendix 5. The reviewers met after extracting

the first five articles to determine if the extraction approach was consistent with the objectives of the study. Working definitions for PSIs and AEs were recorded.

Table 3.2 Main categories for data extraction

Authors	Measurement method
Publication year	Types of patient safety incidents
Discipline	Frequencies of patient safety incidents
Research design	Types of adverse events
Method for data collection	Frequencies of adverse events

3.5.1 Data summary and synthesis

The scoping review method was likely to generate a heterogeneous body of work.[163] As I anticipated this, along with different definitions as discussed in Chapter 1, I did not seek to generate summary estimates of the frequency and burden of PSIs. Instead, following the framework suggested by Levac et al.,[155] one reviewer (myself) conducted conceptual and narrative syntheses[164] from the reported findings. The included articles were read and I developed notes/annotations about recurring themes or concepts. Then, I conducted a preliminary synthesis by developing a conceptual map of the reported PSIs and AEs. Emerging themes or concepts with similar meaning were grouped. Then, based on these conceptual groups, I described frequency ranges of PSIs and AEs. Moreover, identified PSIs and AEs were judged again by EEC and FSO, and proposed as potential NEs if they met the criteria shown in Table 1.5.[87]

3.6 Results

A total of 8386 potentially relevant articles were retrieved from which 40 were included (Figure 3.2). The general characteristics of these articles are displayed in Table 3.2. The relative percentage of the included publications substantially increased from 15.0% (n=6) in the first four years (1994-1998) to 37.5% (n=15) in the last four years (2011-2015). Healthcare systems within high-income economies were the source of the majority of the publications (92.5%, n=37) in which general dentistry ranked as the top discipline (27.5%, n=11), followed by endodontics, legal medicine and studies reporting various disciplines (15.0%, n=6 each). Fewer articles were found for oral surgery (12.5%, n=5), paediatric dentistry (7.5%, n=7.5), implantology (5.0%, n=2) and orthodontics (2.5%, n=1). Most studies concerned private practices (72.5%, n=29)

and dental schools (22.5%, n=9); few were related to outpatient hospital clinics (5.0%, n=2). Documentary review (75.0%, n=30) and structured questionnaires (25.0%, n=10) were used for data collection. The sample sizes varied substantially from 11 to 2,830,000 participants. None of the included articles used a randomised sample.

Figure 3.2 PRISMA diagram

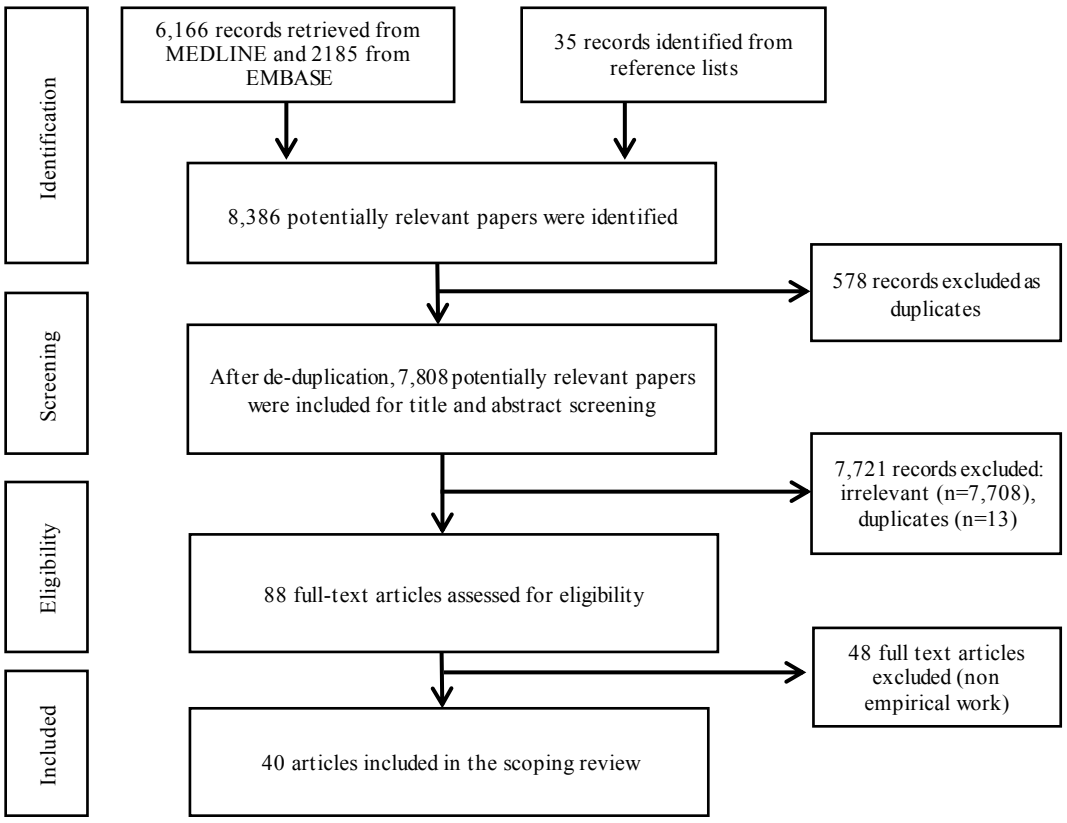


Table 3.3 Characteristics of the included articles in the systematic scoping review

.First author	Reference number	Year	Country	Level of economic development	Discipline	Explicit theoretical framework	Method for collecting data	Measurement methods	Sample size	Sample randomisation
Milgrom, P.	165	1994	USA	HIE	Various	No	SQ	Survey	289	No
Haas, D.A.	166	1995	Canada	HIE	Various	No	Doc. Rev	Malpractice claim analysis	143	No
Lupi, J. E.	167	1996	USA	HIE	Orthodontics	No	Doc. Rev	Radiographic review	88	No
Nkansah P.J.	168	1997	Canada	HIE	Various	No	Doc. Rev	Survey	2830000	No
Keur I.	169	1998	Netherlands	HIE	General dentistry	No	SQ	Survey	471	No
Venta I.	170	1998	Finland	HIE	Legal medicine	No	Doc. Rev	Malpractice claim analysis	237	No
Atherton G.J.	171	1999	UK	HIE	General dentistry	No	SQ	Survey	1110	No
Ammar, WA..	172	2000	Saudi Arabia	HIE	Legal medicine	No	Doc. Rev	Malpractice claim analysis	32	No
Leelataweedwud, P.	173	2001	USA	HIE	Paediatric dentistry	No	Doc. Rev	Record review	195	No
Givol, N	174	2002	Israel	HIE	Implantology	No	Doc. Rev	Malpractice claim analysis	61	No
D´Eramo E.M.	175	2003	USA	HIE	Oral surgery	No	SQ	Survey	157	No
Frangiskos, F.	176	2003	Greece	HIE	Oral surgery	No	SQ	Direct observation	250	No
Tiwana k.K	177	2004	USA	HIE	Various	No	Doc. Rev	Record review	36	No
Ozdemir M.H.	178	2005	Turkey	UMIE	Legal medicine	No	Doc. Rev	Malpractice claim analysis	11	No
Susini, G.	179	2007	France	HIE	Endodontics	No	Doc. Rev	Malpractice claim analysis	24651*	No
Bjorndal, L.	180	2008	Denmark	HIE	Legal medicine	No	Doc. Rev	Malpractice claim analysis	482	No
Tzanetakis G.N.	181	2008	Greece	HIE	Endodontics	No	Doc. Rev	Record review	2180	No

Abbreviations: HIE= high income economies; UMIE= upper middle income economies; LMIE= lower middle income economies; NA=Not applicable; CS=Cross-sectional study; UCT=Uncontrolled clinical trial;; CaCo=Case control study; SQ=Structured questionnaire; Doc. Rev= document review.

First author	Reference number	Year	Country	Level of economic development	Discipline	Explicit theoretical framework	Method for collecting data	Measurement methods	Sample size	Sample randomisation
Kleier, DJ	182	2008	USA	HIE	Endodontics	No	SQ	Survey	314	No
Gaffen, A. S.	183	2009	Canada	HIE	General	No	Doc. Rev	Malpractice claim analysis	182	No
Kiani, M.	184	2009	Iran	UMIE	Legal medicine	No	Doc. Rev	Malpractice claim analysis	157	No
Lee, JJ	185	2009	Taiwan	HIE	Oral surgery	No	Doc. Rev	Malpractice claim analysis	2,223,971	No
Peleg O.	186	2010	Israel	HIE	General	No	Doc. Rev	Malpractice claim analysis	48	No
Tsesis, I.	187	2010	Israel	HIE	Endodontics	No	Doc. Rev	Radiographic review	56175	No
Hisanaga, R	188	2010	Japan	HIE	Various	No	Doc. Rev	Record review	37	No
Givol, N	187	2010	Israel	HIE	Endodontics	No	Doc. Rev	Malpractice claim analysis	720	No
Ashkenazi, M.	189	2011	Israel	HIE	Paediatric dentistry	No	SQ	Survey	85	No
Obinata K.	140	2011	Japan	HIE	General	No	Doc. Rev	Record review	23	No
Perea-Perez B.	190	2011	Spain	HIE	Legal medicine	No	Doc. Rev	Malpractice claim analysis	63	No
Soehardi A.	191	2011	Netherlands	HIE	Oral surgery	No	SQ	Survey	157	No
Hillerup, S.	192	2011	Denmark	HIE	Oral surgery	No	Doc. Rev	Record review	241 & 115	No
Chicka M.C.	193	2012	Canada	HIE	Paediatric dentistry	No	Doc. Rev	Malpractice claim analysis	17	No
Schwamburger N.T.	194	2012	USA	HIE	General	No	Doc. Rev	Record review	1,468	No
Thusu, S.	142	2012	UK	HIE	General	No	Doc. Rev	Incident reports	2,012	No
Abi Najm S.	195	2013	Switzerland	HIE	Implantology	No	Doc. Rev	Record review	83	No
Hashemipour M.A.	196	2013	Iran	UMIE	General	No	Doc. Rev	Malpractice claim analysis	64	No
Hiivala N.	197	2013	Finland	HIE	General	No	SQ	Survey	856	No

Abbreviations: HIE= high income economies; UMIE= upper middle income economies; LMIE= lower middle income economies; NA=Not applicable; CS=Cross-sectional study; UCT=Uncontrolled clinical trial; CaCo=Case control study; SQ=Structured questionnaire; Doc. Rev= document review.

First author	Reference number	Year	Country	Level of economic development	Discipline	Explicit theoretical framework	Method for collecting data	Measurement methods	Sample size	Sample randomisation
Kalenderian, E.	198	2013	USA	HIE	General	Yes	Doc. Rev	Trigger tool	315	No
Pinchi, V.	199	2013	Italy	HIE	Endodontics	No	Doc. Rev	Malpractice claim analysis	120	No
Renton, T.	200	2013	UK	HIE	General & Specialist	No	SQ	Survey	415	No
Perea-Perez B.	201	2014	Spain	HIE	General	No	Doc. Rev	Malpractice claim analysis	415	No

Abbreviations: HIE= high income economies; UMIE= upper middle income economies; LMIE= lower middle income economies; NA=Not applicable; CS=Cross-sectional study; UCT=Uncontrolled clinical trial; CaCo=Case control study; SQ=Structured questionnaire; Doc. Rev= document review.

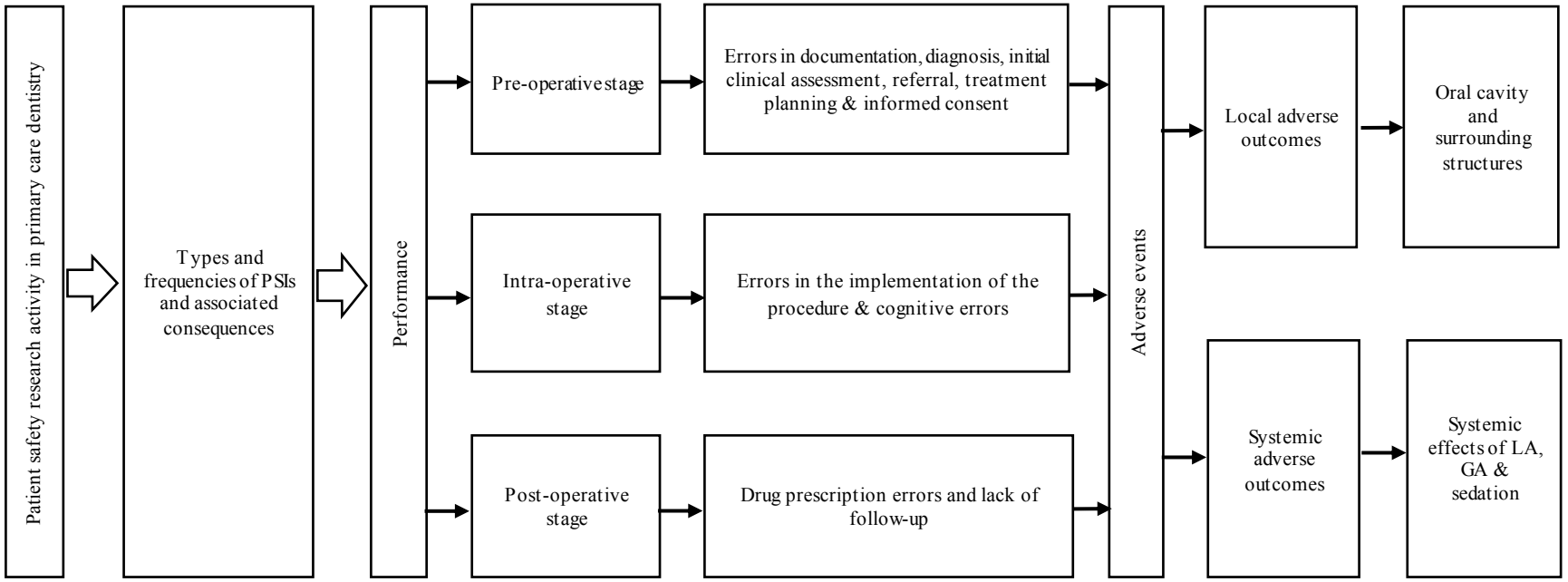
The results were ordered into the conceptual domains displayed in Figure 3.3. Each of these will be described in turn.

3.6.1 Types and frequencies of patient safety incidents

Initially, PSIs were organised across three stages that were conceptualised as the period before clinical treatments were carried out (pre-operative stage), the period of clinical treatment (intra-operative stage) and the period after the clinical treatment (post-operative stage). Then, PSIs and their frequencies were grouped and presented across the main three identified measurement methods (Table 3.3). As discussed in Chapter 1 (section 1.1), the overlapping terminology in patient safety may result in events like wrong-tooth extractions and tooth perforations to be classified as a PSI or an AE, I decided to allocate them as PSIs. This in accordance with the Revised Never Events Policy and Framework[87] which was also discussed in Chapter 1 (section 1.2.2.1). Based on this decision, my results showed that malpractice case reviews and surveys were the methods most frequently used to identify diverse types of PSIs.

Errors concerning administrative processes,[165] examination and diagnosis,[165, 184, 187, 189, 197, 201] treatment planning,[178, 184, 186, 187, 189, 196, 201] communication,[184, 196, 197] informed consent[172, 178, 180, 187, 189] and referral[184, 186, 196] were identified pre-operatively. Examples of errors in referrals and treatment planning resulted in wrong-tooth extractions[186, 202] and jaw fractures,[191] respectively. Intra-operatively, confusion of the operator led to wrong-tooth extractions.[186] Procedural errors included technical errors, broken instruments and tooth perforations.[165, 172, 174, 175, 180, 181, 189, 197, 199, 201] Inhalation and ingestion of foreign objects were related to broken instruments and flaws in handling small objects.[188] Drug prescription errors emerged post-operatively,[165, 180, 189, 201] along with flaws in following-up in patients seeking legal assistance.[165]

Figure 3.3 Conceptual model for the activity in patient safety research in primary care dentistry



Abbreviations: PSIs=patient safety incidents; GA=general anaesthesia, LA=local anaesthesia.

Table 3.4 Variability of frequencies of PSIs across three main measurement methods

	Patient safety incidents	Malpractice case review (n=17)		Surveys (n=10)		Record review (n=8)	
		Ranges (%)	References	Ranges (%)	References	Ranges (%)	References
Pre-operative stage	Administrative errors	------	------	8.3	165	------	------
	Error in examination or diagnosis	11.4-24.0	165, 184, 187, 201	6.7-55.0 PSIs 6.5-8.0 NMs	165, 189, 197	------	------
	Errors in treatment planning	9.1-26.6	178, 184, 186, 187, 196, 201	2.4	189	------	------
	Documentation errors	3.2-55	184, 196, 199	42.0 PSIs 12.0 NMs	189	------	------
	Communication errors	3.2-12.4	165, 184, 187, 196, 201	6.3 PSIs 15.5 NMs	165, 189, 197	------	------
	Informed consent errors	3.1-59.4	172, 178, 180, 187	6.2-11.0 PSIs 4.0 NMs	165, 189	------	------
	Referral	3.1-12.0	184, 186, 196	------	------	------	------
Intra-operative stage	Cognitive failure / action lapse/ confusion	13.0-26.2	186, 187	------	------	------	------
	Procedural errors	5.9-49.0	172, 174, 180, 199, 201	<1.0-49.0 PSIs 5.0 NMs	165, 175, 189, 197	1.8	181
	Local anaesthesia administration errors	41.0	193	<1.0 PSIs 1.3 NMs	197	------	------
	Inhaled & ingested objects	<1.0-18.2	178, 179, 184, 196	<1-12.0 PSIs 9.0-13.9 NMs	171, 175, 189, 197	<1.0	140, 177, 188
	Failure to appropriately treat medically compromised patients	3.8	184	------	------	------	------
	Equipment failure	4.5-7.9	184, 196, 201	30.0 PSIs 18.7 NMs	189, 197	------	------
	Multiple exposure to x-rays	3.7	184, 196, 201	5.6-89.0 PSIs 1.0-5.0 NMs	189, 197	------	------

	Patient safety incidents	Malpractice case review (n=17)		Surveys (n=10)		Record review (n=8)	
		Ranges (%)	References	Ranges (%)	References	Ranges (%)	References
	Sedation errors	------	------	<1-33 PSIs 1.2-6 NMs	165, 175, 189, 197	------	------
	Infection control	------	------	<1 PSIs 5.82 NMs	197	------	------
Post-operative stage	Drug prescription errors	1.68-2.9	180, 201	3.5-32 PSIs 5-19 NMs	165, 189	------	------
	Lack of follow-up	1.63	174	4.8	165	------	-----
Abbreviations: PSIs= patient safety incidents; NMs= near misses							

3.6.2 Types and frequencies of adverse outcomes

A distinction is apparent between local adverse outcomes which concerned the oral cavity and surrounding areas, and systemic adverse outcomes which involved the systemic effects of local anaesthesia (LA), general anaesthesia (GA) and sedation.[41, 43, 45, 63] This finding was considered to group the identified AE outcomes shown in Table 3.4. Then, the variety of adverse outcomes and their frequencies were grouped and presented across the main three identified measurement methods (Table 3.4). When these main methods were compared, my results show that malpractice studies again contributed the most to the identification of adverse outcomes. However, further analysis showed that most adverse outcomes were related to local adverse outcomes or consequences that involved the oral cavity and surrounding areas. Systemic adverse outcomes were less frequently reported and generally identified in surveys and record reviews. Within the category of local adverse outcomes, nerve damage emerged after LA administration or after surgical procedures.[166, 183, 203] For systemic adverse outcomes, cardiovascular events included angina pectoris, myocardial infarction, and stroke[171, 175, 194] Death was reported as a consequence of flaws in LA administration, sedation and GA.[166, 168, 178, 190, 193, 201]

Table 3.5 Variability of frequencies of adverse outcomes across three main measurement methods

	Adverse outcomes	Malpractice analysis (n= 17)		Surveys (n= 10)		Record review (n= 8)	
		Ranges (%)	References	Ranges (%)	References	Ranges (%)	References
Local adverse outcomes	Injuries	1-19	170, 174, 178, 184, 190, 196, 201	<1–14.1 AEs 2.02 NMs	175, 189, 197	14.46	195
	Accidental injection of sodium hypochlorite	-----	-----	2.03	182	-----	-----
	Tooth damage	-----	-----	10.62 AEs 2.5 NMs	197	-----	-----
	Alveolar bone loss	1.63	174, 201	-----	-----	-----	-----
	Nerve damage	<1-59	166, 170, 174, 183, 184, 190, 196, 201	<1	200	75.1	192
	Wrong tooth	3.1-5.7	184, 196	7-31 AEs 1-8 NMs	189	----	----
	Wrong treatment	5.7-15.6	180, 184, 196	1.08 AEs 1.5 NMs	197	-----	-----
	Wrong patient	-----	-----	<1 AEs 6.07 NMs	197	-----	-----
	Wrong body part	3.1-5.7		4.5 AEs 3.5 NMs	197	-----	-----
	Tooth loss	8.8-29.4	180, 184, 190, 196, 201	-----	-----	-----	-----
	Tooth fracture	1.58-8.8	170, 180, 190	52	191, 197	-----	-----
	Infection after treatment	<1-16.8	170, 174, 178, 180, 184, 185, 190, 201	58 AEs 1 NMs	175, 189, 197	-----	-----
	Peri implantitis	-----	-----	-----	-----	2.40	195
	Treatment failure	29.7-37	187, 196	-----	-----	-----	-----
	Temporomandibular joint complication	3.1-14.4	184, 190, 196, 201	-----	-----	-----	-----

	Adverse outcomes	Malpractice analysis (n= 17)		Surveys (n= 10)		Record review (n= 8)	
		Ranges (%)	References	Ranges (%)	References	Ranges (%)	References
	Prolonged pain	2-13.3	172, 180, 184, 196	-----	-----	-----	-----
	Prolonged or additional treatment	3.3-30	180, 184	-----	-----	-----	-----
Systemic adverse outcomes	Adverse reactions to local anaesthesia	<1-4.5	184, 196, 201	<1	171	<1	194
	Allergic reactions	<1	201	<1	169, 171, 197	-----	-----
	Cardiovascular events	-----	-----	<1	171, 175	<1	194
	Diabetic events	-----	-----	<1	169, 171	-----	-----
	Vasovagal collapse /syncope	-----	-----	<1-3.3	169, 175, 197	<1-3.3	194, 203
	Dizziness, headache, nausea or vomiting	-----	-----	-----	-----	<1	173, 194
	Fits/seizures	-----	-----	<1	171, 175	-----	-----
	Asthma or apnoea events	-----	-----	<1-5.5	169, 171	<1	173
	Desaturation	-----	-----	-----	-----	<1	173
	Prolonged sedation	-----	-----	-----	-----	1.53	173
	Brain damage	53	193	-----	-----	-----	-----
	Death	<1-53	166, 178, 190, 193, 201	<1	168	-----	-----
Abbreviations: AEs= adverse events; NMs= near misses							

3.6.3 Potential never events

All the emerging PSIs and adverse outcomes were further assessed for their inclusion in a list of potential NEs. These potential NEs were compared against the NE-criteria shown in Table 3.5. By the conceptualised stages of clinical treatment, I developed a list informed by the three stages of dental surgery shown in Table 3.5.

Table 3.6 List of potential never events for primary care dentistry

Pre-operative stage
Nerve damage due to errors in treatment plan [204]
Intra-operative stage
Injection of wrong anaesthetic solution[197]
Ingestion & aspiration of foreign objects[140, 142, 171, 175, 177-179, 184, 188, 189, 196, 197]
Wrong tooth treated or extracted[142, 180, 184, 186, 196, 197, 201, 205]
Intravascular injection of local anaesthetic[176]
Acrylic set inside the mouth[189]
Jaw fracture due to implant placement[191]
Accidental injection of sodium hypochlorite[182]
Overdose of sedatives[189]
Post-operative stage
Severe apical tooth resorption due to orthodontic treatment[167]

3.7 Chapter summary

The results from this systematic scoping review show that patient safety research in dentistry is limited as most of the current work is descriptive. It is also difficult to generalise from such studies due to differences in underlying definitions, varying methodological approaches, and differing patient populations. The majority of existing work also comes from a limited number of high-income countries. Compared to the progress achieved in secondary care medicine, as discussed in Chapter 1, the field of patient safety in dentistry is in its early development. The main five PSIs identified in the systematic scoping review were a) errors in diagnosis and examination, b) treatment planning, c) communication, d) procedural errors and e) the accidental ingestion or inhalation of foreign objects. However, little attention was paid to wider organisational issues such as flaws within the physical environment, scheduling and patient access, management and associated lines of responsibility, and the influence of policies.

I conducted a comprehensive overview of an under-explored field through systematic methods following published guidelines.[154, 155] The great diversity of study designs, measurement methods, populations studied and sampling strategies did not permit formal statistical comparisons between the included studies in this systematic scoping review. Also, due to the lack of standardised terminology, the search strategy comprised broad terms, in order to retrieve as many potential articles as possible. As discussed in Chapter 1, patient safety concepts in dentistry are, as yet, poorly understood.[25-28] This insufficient understanding was reflected in my systematic scoping review, which revealed differences in definitions or no explicit definitions at all for PSIs or adverse outcomes.

Quality assessment is not a component of scoping reviews and so this step was therefore not undertaken.[163] Therefore, I anticipated retrieval of a wide variety of studies as the scoping review method allowed us to cover broad area of the literature.[163] However, the heterogeneity of evidence also posed challenges for the interpretation of data. In order to address this issue, the emerging AEs and PSIs were grouped into the major concepts shown in Figure 3.3. Individually, I gathered data from each article for specific and narrow objectives, which represented a challenge for data extraction and

to conceptually map and organise the PSIs and AEs. These were also synthesised[164] and integrated in Tables 3.3 and 3.4. Moreover, there was insufficient evidence to either justify a systematic review, meta-analysis or to provide pooled estimates. The results of this systematic scoping review (excluding NEs data), have been published in the Journal of Patient Safety[206]. From the articles included in this systematic scoping review, Thusu et al.[142] made an important contribution as they were first to study secondary data from a PSI-reporting system, the NRLS. Compared with other sources of information,[207] data from incident reporting systems can provide continuous, near real-time insights about diverse PSIs, including near misses. However, their study did not fully characterise the PSI-reports into incidents, their contributory factors and outcomes. Therefore, I believe that more rigorous mixed-methods approaches are needed in order to fully understand and characterise PSI-reports are needed. The rigorous mixed-method approach I used in this PhD will be described in Chapter 4 of this thesis. The results and the conceptual model for the activity in patient safety research (Figure 3.2) were used to provide the evidence-base for the methods and analysis described in Chapter 4.

A set of NEs for primary care dentistry is needed,[144] NEs are entirely preventable high-impact events[19] and the list of potential NEs that I identified in my systematic scoping review (Table 3.4) was used to provide the evidence-base for the third and final stage of my PhD, which is described in Chapter 5. In the following chapter I will describe the process I followed to understand the value of PSI-reports from dentistry in the NRLS. This process includes the characterisation of these reports into their types, contributory factors, outcomes and their severity.

Chapter 4 . Mixed-methods characterisation and analysis of patient safety incident reports from primary care dentistry

4.1 Introduction

The results described in Chapter 3 show that the majority of patient safety research in primary dental care is descriptive, with a variety of approaches to the terminology, the study designs and differing patient populations. Based on the findings of the systematic scoping review, the most reported PSIs were related to diagnosis and examination, treatment planning, communication, procedural errors and the accidental ingestion or inhalation of foreign objects.[206] Although this systematic scoping review brings an important contribution to the evidence base for patient safety research in dentistry, the identification of the main risks to patient safety in dentistry remains to achieved.[151] Data already available from incident reporting systems brings an opportunity to expand the evidence base further. This contribution to the evidence base can be achieved by exploring a range of incident reports submitted to one of the most comprehensive databases for PSI-reports, the NRLS. Data analysis of incident reports has brought an initial understanding to patient safety in primary care.[208-212] Unfortunately, only two studies have assessed this resource in dentistry.[142, 143] The study conducted by Thusu et al.[142] as identified in Chapter 3, brought an initial categorisation of PSIs and their outcomes. However, the study conducted by Renton and Sabbah,[143] published after the screening period of my systematic scoping review, only analysed serious incidents and NEs. Although these studies represented welcomed steps, they did not use rigorous mixed-methods approaches to fully understand and characterise the existing PSs, their contributory factors the resulting outcomes in primary care dentistry. Previous mixed-methods studies analysing general practice PSI-reports within the NRLS have shown their utility to categorise PSIs and identify patterns of contributory incidents and contributory factors.[208-212] This current chapter provides a description of the approach I followed in order to a) understand the value of secondary data from a comprehensive incident reporting system, b) to characterise dentistry-related PSIs and c) to identify key areas for research and intervention.

4.2 Aims

This chapter addresses the following aims:

- To understand the nature of PSI reports from dentistry in the NRLS and provide insights into the nature and type of PSIs and their outcomes;
- To identify contributory factors to PSIs;
- To identify the more frequent and severe threats to patient safety in primary care dentistry, and with the greatest, opportunity for improvement

4.3 Objectives

This chapter addresses the following objectives:

- Characterise the reports submitted to the NRLS into categories and subcategories of PSIs, contributory factors, outcomes and degree of harm
- Identify patterns in chronological order of multiple incidents with their related contributory factors

4.3 Methods

I conducted a two-stage exploratory sequential mixed-methods study of a patient safety incident database with a selected sample of reports from primary care practices selected for analysis. This design combined a detailed data coding process and iterative generation of data summaries using both descriptive statistical and thematic analysis methods.[128]

4.3.1 Ethics

Ethical approval for this research was obtained from the University of Edinburgh's Centre for Population Health Sciences Research Ethnics Committee (Appendix 7).

4.3.2 Data source (National Reporting Learning System)

The data source for this study was the PSI reports submitted to the NRLS. As discussed in Chapter 1, the NRLS is a national reporting system created in 2003 for the NHS in England and Wales and it is one of the most comprehensive reporting systems worldwide.[96, 97] The NRLS consists of a database of incident reports which are submitted from NHS healthcare organisations. Patients and other members of the public can also submit online reports directly to the NHS. The NHS definition for the reported PSIs refers to *"any injury or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare*",[142] a definition closely allied to my preferred terminology as show in Chapter 1 (see Table 1.1 and Appendix 1). Although the incident reporting was initially voluntary, since 2010 the reporting of any incidents that resulted in severe patient harm or death has been mandatory.[213] The reports contain categorical data (e.g. age, incident location and severity of harm) and three unstructured free-text fields to encourage the individual(s) reporting to provide a narrative description of the event, its perceived causes and any potential preventive measures.[128] Incident reports containing details relating to severe harm and/or death are analysed by NHS staff and safety experts to identify opportunities for the continuous improvement of NHS-healthcare. A more detailed description of the database has been reported previously.[214]

4.3.2.1 Sample selection

I initially received 42,729 reports that covered a period of 8 years (between April 2005 and September 2013) from general practice in England and Wales. I considered these to be a complete data set. To include any PSI-reports related to primary dental care services, I applied filters for pre-coded NHS categories "Primary care setting" for the column titled INO5 Location (Lvl2) and "Dental surgery" for the column titled INO3 Location (Lvl3). As a result, I obtained a sample of 11,836 records. A more detailed review of these 11,836 reports still showed the presence of reports not related to dentistry; e.g. incidents related to pressure sores, podiatry procedures and patient's residences. Therefore, I decided to further revise the filtered reports (n= 11,836) and exclude those not related to dentistry. I achieved this reduction by reading the narrative descriptions and, based on my clinical experience, decided whether the reports were suitable for inclusion or elimination. As a result, a revised sample of 4,247 reports was

obtained, which was used for the initial pilot thematic analysis in the first stage of my study.

Apart from the pilot thematic analysis, I also assessed the 4,247 reports to describe their distribution by year and degree of harm using the pre-coded categories allocated in the NRLS (see Table 4.1).

Table 4.1 Frequency distribution per year and degree of harm as pre-coded by the NHS

	Degree of harm					
Period	No Harm	Low	Moderate	Severe	Death	Grand Total
2005	81	20	8	3	1	113
2006	154	77	24	1	1	257
2007	148	66	21	2	1	238
2008	275	108	20	2		405
2009	428	154	32	4	1	619
2010	556	162	27	3	2	750
2011	505	157	23	7		692
2012	437	184	40	6		667
2013	339	139	26	2		506
Grand Total	2923	1067	221	30	6	4247

Given the time required to read and code each narrative description, I decided to obtain a randomised sample of 2,000 reports, weighted by year and severity of harm. I used this approach to ensure the more recent report (2012-2013) and those referring to more harmful incidents. Similar approaches have been used previously.[128] To achieve this selection, all the "moderate", "severe" and "deaths" cases (n=257) were chosen for inclusion from the 4,247 reports in the final sample. Then, proportions per year and degree of harm were obtained for the remaining 3,990 reports (Table 4.2).

Table 4.2 Frequencies and proportions of the total 3,990 of "low" and "no harm" incident reports as pre-coded by the NHS

Period	Frequencies		Percentage	
	Low	No Harm	Low	No Harm
2005	20	81	1.9	2.8
2006	77	154	7.2	5.3
2007	66	148	6.2	5.1
2008	108	275	10.1	9.4
2009	154	428	14.4	14.6
2010	162	556	15.2	19.0

Period	Frequencies		Percentage	
	Low	No Harm	Low	No Harm
2011	157	505	14.7	17.3
2012	184	437	17.2	15.0
2013	139	339	13.0	11.6
Total	1067	2923	100	100

From these reports, 1,743 'low' and 'no harm' reports were selected to complete the final sample of 2,000 reports. To achieve this selection, the required reports were weighted by year and randomly selected by obtaining similar proportions when compared to the 3,990 reports (Table 4.3). The process for obtaining this randomised sample weighted by year and the severity of harm was aided by an actuary.

Table 4.3 Distribution of frequencies and percentages of the required 1,743 patient safety incident-reports weighted by year and degree of harm

	Frequencies		Percentage	
Period	Low	No Harm	Low	No Harm
2005	7	38	1.5	3.0
2006	23	63	4.9	5.0
2007	34	58	7.2	4.6
2008	48	117	10.1	9.2
2009	73	187	15.4	14.7
2010	75	250	15.8	19.7
2011	65	219	13.7	17.3
2012	88	187	18.6	14.7
2013	61	150	12.9	11.8
Total	474	1269	100.0	100

4.3.3 Data processing

For the **first stage** of this study, I undertook a pilot analysis involving 300 of the initial 4,247 reports. This analysis involved the development and application of initial codes to bring structure to the narrative descriptions and to describe the types of PSIs, contributory incidents (if applicable), contributory factors and their reported outcomes. During the application of the initial codes, these and other emerging codes were constantly compared against current topics or themes from other patient safety classification systems. These systems included the WHO ICPS,[20] the LINNEAUS

Patient Safety Classification for Primary Care,[132] and the Primary Care Patient Safety (PISA) Classification System.[134] Also included were the results obtained from the systematic scoping review,[206] described in Chapter 3. This iterative comparison of classification systems against the emerging codes resulted in three coding frameworks to describe a) what happened i.e. type of incident (Appendix 8), b) perceived reasons the incident occurred i.e. contributory factors (Appendix 9) and c) incident outcomes (Appendix 10). These frameworks present a hierarchical arrangement of first- and second-level codes that were continuously refined in the second stage of the study, being applied to the weighted randomised sample of 2,000 reports.

The **second stage** of this study consisted of a quantitative exploratory descriptive analysis[215] of the 2,000 free-narrative descriptions. To achieve this analysis, the reports were coded by the author (EEC) and a trained second coder (AS). The second coder was provided with a training sample of 300 reports and discussed the challenges and additional improvements to the coding frameworks. Also, following the method described by Rees et al.,[209] we applied the nine rules of the Recursive Model of Incident Analysis[216] as developed by the Australian Patient Safety Foundation, were applied in order to structure the coding process (see Appendix 11). Based on this analysis, between one to four codes in chronological order were applied to describe both incidents and potential contributory factors (see Figure 4.1).

The main incident was labelled as a "primary incident", then "contributory incidents" were defined as those incidents preceding the primary incidents. "Contributory factors" were defined as any condition that influenced the occurrence of the primary incidents.[29] Coding of the free-text narrative descriptions allowed the categorisation of reports by incident type, potential contributory factors, outcome and severity of harm. This categorisation provided the basis for the subsequent data analysis. Severity of harm was assessed using the WHO's ICPS definitions (see Table 4.4).[20]

Figure 4.1 Coding process based on the Recursive Model of Incident Analysis

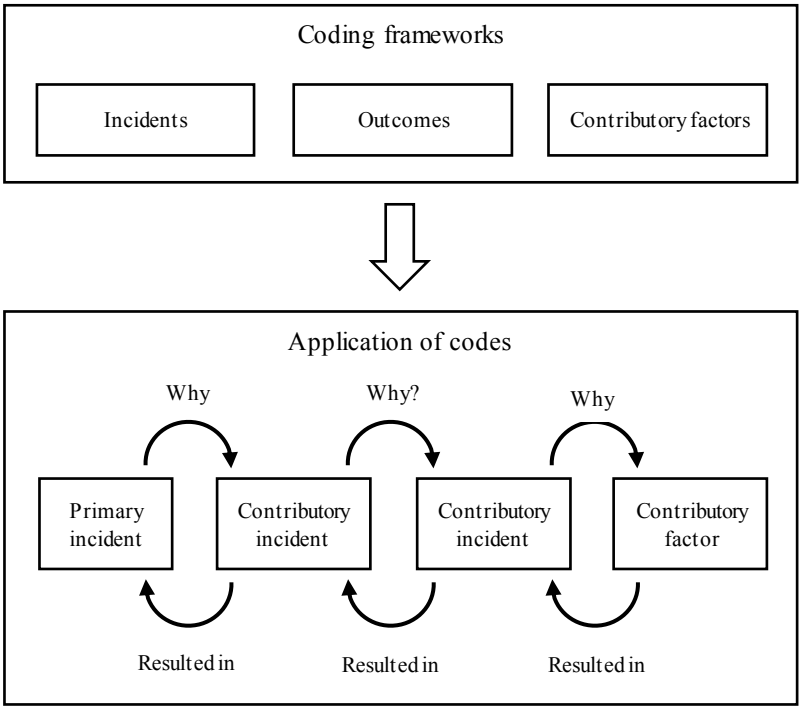


Table 4.4 The WHO's criteria for describing the severity of harm [20] and its application using dentistry-related examples.

Severity of harm	Definition	Examples in dentistry
No harm	Patient outcome is not symptomatic, and no treatment is required	Patient's lip got accidentally caught by hand piece bur without any visible injury
Low harm	Patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal and intermediate but short term, and no or minimal intervention is required	Contact of etching gel to the oral mucosa during procedure
Moderate harm	Patient outcome is symptomatic requiring intervention, an increased length of stay, or causing permanent or long-term harm or loss of function	Fracture of the maxillary or mandible during surgical procedure
Severe harm	Patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long-term harm or loss of function	Non-fatal anaphylactic reaction to local anaesthesia that resulted in hospitalisation
Death	On the balance of probabilities, death was caused or brought forward in the short term by the incident	Fatal anaphylactic response to local anaesthesia

To assess the inter-coder reliability, twenty percent (n=400) of the reports were double coded (EEC and AS) and Cohen's Kappa statistic[217] was calculated for the primary incident type and which were the closest reported incidents to the outcome experienced by the patient and contributory factors. The Kappa statistic is a measurement introduced by Jacob Cohen in 1960[218] which determines the extent to which the agreement between two coders, who are working with categorical data, can be reproduced. For this study, a Kappa of >0.7 was sought between the two coders. The interpretation of Cohen's Kappa statistic is shown in Table 4.5. Disagreements in coding were arbitrated by a third person.

Table 4.5 Interpretation of Cohen's Kappa statistic

Value of Kappa	Level of agreement	Percentage reliable data
0.0-0.20	None	0.0 - 4.0
0.21-0.39	Minimal	4.0 - 15.0
0.40-0.59	Weak	15.0 - 35.0
0.60-0.79	Moderate	35.0 - 63.0
0.80-0.90	Strong	64.0 - 81.0
Above 0.90	Almost perfect	82.0 - 100

Extracted from McHugh et al,[217]

4.3.3 Analysis and interpretation of data

The qualitative codes were extracted into Excel 2013.[162] Then, as previously described in the **second stage** for data processing, I undertook an exploratory, descriptive analysis[215] to generate descriptive summaries for the most frequent incident types, contributory factors, types of outcomes and degrees of harm was carried out. This procedure allowed me to identify priority areas based on: (i) the more frequent incidents; and (ii) the most harmful outcomes that resulted in moderate harm, severe harm or death. Then, I cross-tabulated primary incident types with the degree of harm, in order to identify potential relationships in the data. These cross-tabulations allowed me to identify the most harmful incidents and further investigate the role of contributory incidents and contributory factors. Additional patterns in the data were identified by assessing all the frequencies of combinations of incidents and contributory factors (e.g. primary incident + secondary incident + contributory factor).

During the data coding and following the method used by Rees et al.,[209] I identified a purposive sample of the more frequent incidents per clinical stage that cross-tabulated with available contributory incidents, contributory factors and their outcomes. The corresponding reports were further thematically analysed and re-read to strengthen my familiarisation with the data. If needed, new codes were created to capture additional semantic (descriptive and superficial) insights and latent (underlying or inferred) insights present in the narrative descriptions and the circumstances (context) in which the incidents occurred.[152, 219] All the codes were grouped into themes and sub-themes to support my understanding of both the data and the underlying reasons for incidents that might not have been captured by the quantitative data.[152, 219]

4.4. Results

Of the 2,000 randomised reports, 1,456 were included in the quantitative analysis. Reports were excluded if they did not describe a PSI (n=311), were not related to dentistry (n=125), concerned patient falls (n=31), contained insufficient details (n=23), dentist harmed rather than patient (n=18), or were about general non-specific complaints (n=6). Cohen's Kappa (k) statistic for inter-rater coding reliability for primary incidents was high (k=0.860; p<0.01). Data about the patients' demographics, outcomes and actions for recurrence was largely unstructured and missing for more than 50% of the reports. Table 4.6 shows the distribution of reports per discipline using pre-coded NHS categories.

Table 4.6 Distribution of patient safety incidents per discipline by pre-coded NHS data

Discipline	Frequency	Percentage
Other	1425	71.3%
Oral surgery	176	8.8%
Restorative dentistry	78	3.9%
Missing	75	3.8%
Endodontics	67	3.4%
Orthodontics	45	2.3%
Dental surgery	41	2.1%
Paediatric dentistry	34	1.7%
Dental medicine	23	1.2%
Periodontics	15	0.8%
Maxillofacial / oral surgery	11	0.6%
Radiology	10	0.5%
Grand Total	**2000**	

4.4.1 Overview of primary incident types and related harm

Table 4.7 shows a description of identified incidents, which occurred in the pre-operative (40.3%; n=587), intra-operative (56.1%; n=817) and post-operative (3.6%; n=52) stages of dental care delivery. All the possible combinations of contributory incidents and contributory factors per clinical stage are available in Appendices 12-14. Regardless of the clinical stage, the main five incident types were: i) delays in treatment (22.9%; 333/1,456), ii) procedural errors (15.1%; 220/1,456), iii) medication-related adverse incidents (11.0%; 160/1,456), iv) equipment failure (6.2%; 90/1,456) and v) errors in obtaining or processing x-rays (6.0%; 87/1,456). Of the 1,456 incidents, 5.3% led to harmful outcomes (77/1,456). Of these harmful outcomes, the main incidents were wrong-tooth extractions (48.1%; 37/77), medication-related adverse incidents (29.9%; 23/77) and procedural errors (13.0%; 10/77).

Table 4.8 shows the characterisation of outcomes. Patient outcomes following an incident were not described for 40.0% of the reports (583/1,456). The most commonly described outcomes were increased documentation/follow-up (12.4%; 181/1,456), laceration/bleeding (99/1,420; 6.8%), delays in using the dental clinic (5.8%; 85/1,456), unnecessary x-ray exposure (5.1%; 74/1,456) and repeated procedures/additional treatment (4.9%; 71/1,456). The majority of outcomes resulted in either no harm or low harm (94.7%; 1,379/1,1456). The majority of harmful incidents were due to wrong-tooth extractions (48.1%; 37/77) and this meant the patient required further unnecessary procedures (91.9%; 34/37). Medication-related adverse incidents (29.9%; 23/77) resulted in paresthesia (21.7%; 5/23), vasovagal responses (17.4%; 4/23) and anaphylaxis (13.0%; 3/23). The more frequent incident types with their respective contributory incidents, contributory factors and outcomes are described below.

Table 4.7 Distribution of primary dental care incidents and related harm by clinical stages

	No harm	Low harm	Moderate harm	Severe	Death	Total	Harmful outcome (n)	Harmful outcome (%)
Preoperative stage	**578**	**7**	**1**		**1**	**587**	**2**	**0.3**
Delays in treatment	332	1				333	0	0.0
Incorrect or unavailable documentation	49					49	0	0.0
Breaches of confidentiality	28					28	0	0.0
Errors in managing appointments	19					19	0	0.0
Errors in the logistics for transporting patients	16					16	0	0.0
Inefficient transfer of information between healthcare settings	15					15	0	0.0
Record not up to date or information missing	12	2	1			15	1	6.7
Insufficient supplies	13					13	0	0.0
Ability to access the dentist	10					10	0	0.0
Inaccurate information on record	10					10	0	0.0
Dental laboratory errors	9					9	0	0.0
Professionalism issue	7	1				8	0	0.0
Errors in choosing the correct process or procedure	7	1				8	0	0.0
Incomplete referral	8					8	0	0.0
Insufficient assessment in history /examination	6					6	0	0.0
Communication errors between dentist and patient	6					6	0	0.0
Communication errors between professionals	5					5	0	0.0
Delayed referral	4	1				5	0	0.0
Wrong medical record	5					5	0	0.0
Errors in obtaining the informed consent	3					3	0	0.0
Communication errors between staff and patients	3					3	0	0.0
Interpreter services not available or non-attendance	2					2	0	0.0
Information filled incorrectly	2					2	0	0.0

	No harm	Low harm	Moderate harm	Severe	Death	Total	Harmful outcome (n)	Harmful outcome (%)
Inaccurate laboratory test results	2					2	0	0.0
Errors in the process of payment systems	2					2	0	0.0
Unnecessary referral	1					1	0	0.0
Delayed assessment	1					1	0	0.0
Failure to follow-up		1				1	0	0.0
Missed diagnosis					1	1	1	100.0
Delayed diagnosis	1					1	0	0.0
Intraoperative stage	**434**	**311**	**69**	**1**	**2**	**817**	**72**	**8.8**
Procedural errors	72	138	10			220	10	4.5
Medication-related adverse incidents	5	132	21		2	160	23	14.4
Equipment failure	85	5				90	0	0.0
Errors in obtaining or processing x-rays	87					87	0	0.0
Broken instrument	79	4				83	0	0.0
Ingestion / inhalation of foreign body	36	6				42	0	0.0
Wrong tooth extracted	2		37			39	37	94.9
Failure to comply with infection control standard procedures	30					30	0	0.0
Other procedural complications	6	18	1	1		26	2	7.7
Insufficient supplies	11					11	0	0.0
Procedure performed on wrong anatomical side or site	6	5				11	0	0.0
Errors in the process of administering a medication	8					8	0	0.0
Errors in obtaining a biopsy	1	1				2	0	0.0
Supplies out of date	1					1	0	0.0
Lost equipment	1					1	0	0.0
Unexpected movement from staff		1				1	0	0.0
Wrong instrument used	1					1	0	0.0

	No harm	Low harm	Moderate harm	Severe	Death	Total	Harmful outcome (n)	Harmful outcome (%)
Contraindicated dental material used	1					1	0	0.0
Equipment not available	1					1	0	0.0
Errors in choosing the correct process or procedure	1					1	0	0.0
Complication as a result of the dental material used		1				1	0	0.0
Postoperative	**46**	**3**	**3**			**52**	**3**	**5.8**
Contraindicated medication prescribed / dispensed	12	1	2			15	2	13.3
Errors in the process of delivering a medication	10					10	0	0.0
Wrong dose prescribed	7					7	0	0.0
Medication incorrectly stored	5					5	0	0.0
Wrong medication / treatment given	4					4	0	0.0
Unintentional drug overdose (self-administered)	3	1				4	0	0.0
Medication not available	3					3	0	0.0
Lost prescription	2					2	0	0.0
Wrong medication prescribed		1				1	0	0.0
No medication/treatment given when appropriate			1			1	1	100.0
Total	1058	321	73	1	3	1456	**77**	5.3

Table 4.8 Characterisation and distribution of outcomes within the analysed patient safety incident reports per degree of harm

Types of outcomes	No harm	Low harm	Moderate harm	Severe	Death	Total	Harmful outcomes (n)	Harmful outcomes (%)
Incident occurred but no outcome	583					583		0.0
Organisational inconvenience	**290**	**14**	**2**			**306**	**2**	**0.7**
Increased documentation / follow-up	169	11	1			181	1	0.6
Delays in using the dental clinic	84					84		0.0
Long wait for service	22					22		0.0
Treating patients without sufficient information	14	2				16		0.0
Legal implication	1	1	1			3	1	33.3
Inconvenience to patients (non-clinical)	**144**	**15**	**37**			**196**	**37**	**18.9**
Unnecessary x-ray exposure	74					74		0.0
Repeated procedures / additional treatment	59	9	3			71	3	4.2
Unnecessary procedures	11	6	34			51	34	66.7
Local outcomes	**28**	**144**	**17**			**189**	**17**	**9.0**
Laceration/bleeding	9	88	2			99	2	2.0
Chemical injury	8	14				22		0.0
Thermal injury		15	1			16	1	6.3
Localised pain / discomfort	5	7	1			13	1	7.7
Extended paraesthesia		6	5			11	5	45.5
Bruises	3	3				6		0.0
Skin tear	1	4				5		0.0

Types of outcomes	**No harm**	**Low harm**	**Moderate harm**	**Severe**	**Death**	**Total**	**Harmful outcomes (n)**	**Harmful outcomes (%)**
Fracture	1		4			5	4	80.0
Needle stick injuries		3				3		0.0
Localised pain/discomfort	1	1				2		0.0
Necrosis of soft-tissues			2			2	2	100.0
Localised Post treatment infection / abscess			2			2	2	100.0
Affection of the temporomandibular joint		1				1		0.0
Localised bleeding		1				1		0.0
Localised swelling		1				1		0.0
Systemic outcomes	**12**	**144**	**17**	**1**		**174**	**18**	**10.3**
Vasovagal response	1	51	4			56	4	7.1
Faint / loss of consciousness	6	36	2			44	2	4.5
Seizure	2	19				21		0.0
Dizziness	3	14				17		0.0
Anaphylaxis		10	6	1		17	7	41.2
Difficulty to breathe		7	1			8	1	12.5
Prolonged sleep / unarousable after sedation		3				3		0.0
Cardio-respiratory arrest			2			2	2	100.0
Nausea / vomiting		2				2		0.0
Methaemoglulinaemia			1			1	1	100.0
Angina attack			1			1	1	100.0
Rash		1				1		0.0
Laryngospasm and bronchospasm		1				1		0.0
Psychological / emotional distress	**1**	**4**				**5**		**0.0**

Types of outcomes	No harm	Low harm	Moderate harm	Severe	Death	Total	Harmful outcomes (n)	Harmful outcomes (%)
Death					**3**	**3**	**3**	**100.0**
Total	1058	321	73	1	3	1456	**77**	5.3

4.4.2 Pre-operative incidents

Delays in a treatment (333/587; 56.7%) were the main incident within the pre-operative stage (see Table 4.4). When available, frequent *contributory incidents,* or those incidents preceding the primary incidents, were a) the patient's inability to access the dentist (102/333; 30.6%) (Example 1 in Box 4.1), b) errors in managing appointments (53/333; 16.8%) (Example 2 in Box 4.1), and c) errors in the logistics of transporting patients (25/333; 7.5%) (Example 3 in Box 4.1). C*ontributory factors* included i) insufficient staff members (111/333; 33.3%) (Example 4 in Box 4.1), ii) lack of equipment maintenance (15/333; 4.5%) and iii) lack of supplies (10/333; 3.0%). Delays in treatment mostly resulted in increased documentation/follow-up (76/333; 22.8%) (Example 5 in Box 4.1) and repeated procedures/additional treatment (15/333; 4.5%) (Example 6 in Box 4.1).

The second most common pre-operative incident was **incorrect or unavailable documentation** (49/587; 8.3%). The main *contributory incidents* resulted from IT-software errors (11/49; 22.4%) (Example 7 in Box 4.1). Incorrect or unavailable documentation mostly led to increased documentation/follow-up (7/49; 14.3%) (Example 8 in Box 4.1) and delays in using the dental clinic (5/49; 10.2%) (Example 9 in Box 4.1). The third most common pre-operative incident was **breaches of confidentiality** (28/587; 4.7%)**.** The main *contributory incidents* were inefficient transfer of information between healthcare settings and wrong medical records (2/28; 7.1% each) (Example 10 in Box 4.1). Main *contributory factors* were failure to adhere to procedures or regulations (14/28; 50.0%) (Example 11 in Box 4.1) and distraction (4/28; 14.3%). One breach of confidentiality resulted in legal implications (1/28; 3.6%) (Example 12 in Box 4.1).

4.4.3 Intra-operative incidents

The main intra-operative incidents were **procedural errors** (220/817; 26.9%). C*ontributory incidents* included equipment failure (20/220; 9.1%) (Example 13 in Box 4.1) and insufficient assessment in history/examination (5/220; 2.3%). The main contributory factors were i) distraction (68/220; 30.9%) (Example 14 in Box 4.1), ii) unexpected movement from the patient (23/220; 10.5%) (Example 15 in Box 4.1) and iii) inadequate skills/knowledge (20/220; 9.1%). Procedural errors mostly led to a)

laceration/bleeding (93/220; 42.3%) (Example 16 in Box 4.1), b) chemical injuries (21/220; 9.5%) (Example 17 in Box 4.1), c) repeated procedures/additional treatment (17/220; 7.7%) (Example 18 in Box 4.1) and d) thermal injuries (14/220; 6.4%) (Example 19 in Box 4.1).

The second most common intra-operative incident were **medication-related adverse incidents** (160/817; 19.6%). C*ontributory factors* included the patient's previous health-related conditions (22/160; 13.8%) (Example 20 in Box 4.1) and non-compliance from the patient (9/160; 5.6%) (Example 21 in Box 4.1). Medication-related adverse incidents mostly led to vasovagal response (51/160; 31.9%) (Example 22 in Box 4.1) or fainting/loss of consciousness (35/160; 21.9%) (Example 23 in Box 4.1). The third most common intra-operative incident was related to **equipment failure** (90/817; 11.0%). The main *contributory factors* were lack of equipment maintenance (40/90; 44.4%) (Example 24 in Box 4.1) and poor equipment design (6/90; 6.7%). Equipment failure mostly led to delays in using the dental clinic (31/90; 34.4%) (Example 25 in Box 4.1).

4.4.4 Post-operative incidents

Main post-operative incidents were due to **contraindicated medications being prescribed/dispensed** (15/52; 28.8%). The main *contributory incident* was insufficient assessment in history/examination (3/15; 20.0%) (Example 26 in Box 4.1). C*ontributory factors* included the patient's previous history on allergies (7/15; 46.7%) (Example 27 in Box 4.1) and distraction (3/15; 20.0%) (Example 28 in Box 4.1). Contraindicated medications being prescribed or dispensed mostly led, in most cases, to increased documentation or follow-up and anaphylaxis (3/15; 20.0% each) (Example 29 in Box 4.1). The second most common post-operative incident resulted from **errors in the process of delivering a medication** (10/52; 19.2) (Example 30 in Box 4.1). Most of these reports did not describe harmful outcomes (8/10; 80.0%).

Box 4.1 Free-text examples of key incidents.

These are extracts from the free-text narrative descriptions of patient safety incidents reported to the National Reporting Learning System. The extracts have been edited by the author to correct typographical errors and remove indecipherable text.
Pre-operative stage
Example 1. The dentist rang the clinic, said he was on his way in but had a call to go back home to help with the family (sickness of relative). The dentist said he was sorry for the late call and could we let (person's name) know that said he (the dentist) would definitely be in tomorrow.
Example 2. Due to a communication breakdown, the dental nurse and dentist left for an appointment offsite without realising that the patient, who was due to be seen, had arrived early onsite with her mother and had been overlooked. This meant that the patient was not able to be seen that day.
Example 3. Patient was taken to wrong clinic by transport and was left with her carer to walk to the actual clinic. The patient was left waiting for 1 hour 50 mins before the transport collected her after 2 phone calls to ask pick up time which was 1120hr - one hour after appointment time. The patient was eventually collected by transport.
Example 4. The dental nurse called in sick. Patients had to be cancelled as an agency nurse was not available. The senior nurse was unable to step in as it was her paperwork day.
Example 5. Patient double booked by dental nurses. The appointment was cancelled at short notice 1 hour prior to the scheduled visit. Request to cancel delegated to reception staff. The patient was contacted by consultant and reassurance was given to address this.
Example 6. The Senior Dental Officer expected to find the lab work for his patient as it was due to be fitted at the next appointment, but it was discovered that it had not been delivered. The Senior Dental Officer telephoned the laboratory and they informed him that the work in question had gone missing at the lab. The lab suggested that an ex - worker at the premises may have been responsible for the missing work, or may have sabotaged the work. The lab apologised, offered to re - start the work and to prioritise the job.
Example 7. I was unable to view a letter regarding a patient on the computer. We tried to read the letter on the computer in the office in (name of clinic) and then on the two computers on the dental reception, but were unable to operate the file, despite clicking on the letter etc. Eventually, a dental nurse was able to access the letter from the clinic. This is unacceptable when trying to view information directly relating to a patient's management.
Example 8. Unable to access patient's radiographs from September 09. Attempted at 10:20m, still unavailable 12:25 at end of appointment. The patient had to be reappointed to complete the treatment plan as a consequence.
Example 9. R4 system running very slowly and erratically throughout the day. Difficulty in accessing patient records and very difficult writing up notes. Delay in seeing patients and extra work for clinician. Stressful.

These are extracts from the free-text narrative descriptions of patient safety incidents reported to the National Reporting Learning System. The extracts have been edited by the author to correct typographical errors and remove indecipherable text.
Example 10. Email containing patient identifiable information (first name and referral dates) was forwarded to an incorrect staff member due to similar names. The staff member was notified by the sender and deleted the information with immediate action. Provider governance and information governance informed, voice mail left for director of clinical services/line manager. Under pressure from several deadlines and doing more than one task on the PC at once. No surname, address to NHS number were included in this email.
Example 11. During clinical waster audit, 2 black bags opened to look at contents, patients' letter with full details of name, address and all clinical details. Also patient address labels for another patient. Black waste is destroyed in land fill sites. Breach of confidential information.
Example 12. Confidentiality breach to GP and family members of HIV status by Dental clinic. Incident being investigated as Serious Incident.
Intra-operative stage
Example 13. (Name of dental clinic) - Whilst patient under sedation undergoing procedure part, the bur detached from hand piece and disappeared suction checked and mouth checked. Bur not located, procedure stopped and patient's was father informed.
Example 14. The dentist asked for a saline solution in a syringe to irrigate a socket after extraction. I accidentally gave him sodium hypochlorite in a syringe labelled sodium hypochlorite. I handed the syringe to the dentist which he used to irrigate the socket, then by the smell he realised that it wasn't the saline solution and he informed me. I went and got the saline and put it in a syringe and handed it to the dentist and he used it to irrigate the socket.
Example 15. The floor of the patient's mouth has been cut by a high speed diamond bur approximately 5mm in length sublingually in LR5 / 6 area. Pt jerked during treatment causing hand piece to slip, thus, causing wound.
Example 16. Dentist slipped with luxator during dental extraction and cut the lingual artery, the bleeding stopped after 2 sutures.
Example 17. During root canal treatment, needle containing hypochlorite, came away from the syringe, causing spillage. The patient was wearing rubber dam & safety goggles, however he felt that some solution had passed into his left eye. Advice was sought from ophthalmology – the eye was washed with running water & saline – the patient is to attend A&E & eye clinic if necessary.
Example 18. Patient stated she had been attending for regular check-ups, and declared dentally fit, until the single handed general dental practitioner retired. On a recent routine visit to locum dentist, patient told she needs emergency treatment or risks loss of some teeth, crowns poorly fitted and

These are extracts from the free-text narrative descriptions of patient safety incidents reported to the National Reporting Learning System. The extracts have been edited by the author to correct typographical errors and remove indecipherable text.
inappropriate anyway, may need dentures, the patient is only in her 40's. Apparent poor performance of previous general dental practitioner.
Example 19. The patient sustained a burn to the lip with heated excavator whilst removing excess of gutta percha. The excavator burnt through the rubber dam but was not noticed as the patient was under local anaesthesia. The patient was informed and Vaseline was applied to the area.
Example 20. The patient attended to dental clinic for routine care. Following the administration of local anaesthetic, the patient began wheezing. Asthmatic patient.
Example 21. The patient suffered hypoglycaemic attack at 4:45pm after we had finished dental treatment. The patient had extreme shaking, her speech was extremely slurred. The patient had not eaten since 11:30, the patient felt unwell whilst we were doing dental treatment, but she didn't want to stop us. We observed the patient whilst she recovered and escorted her home. The patient suffered a hypoglycaemic attack and was given to glucose drinks, hypostop and some chocolate.
Example 22. The patient was given topical anaesthetic followed by infiltration of local anaesthetic. After approximately 3-4 minutes, the patient looked unwell and head started to roll grey and sweaty. No recovery with oxygen and worsened on sitting upright again.
Example 23. I gave a right inferior dental block. A few minutes later, the patient lost consciousness, rolled eyes, went stiff and slumped. The effect lasted less than a minute. The patient was very pale, on regaining consciousness, the patient did not remember. The treatment proceeded uneventfully.
Example 24. A leak from the 3in1 equipment. It leaked during a patient having treatment and the patient was unhappy about getting soaked. I had not noticed sooner that there was a problem with the equipment. The problem with the equipment should have been reported when it was first noticed and not left until a patient made a complaint. Staff meeting held. All staff to report any equipment problems straight away to the practice manager.
Example 25. I gave the patient local anaesthetic but the portable suction started to fail whilst the nurse was trying to aspirate. Treatment could not be completed in surgery 3. Surgery 1 had a free bay, therefore, the patient had to be transferred to surgery 1 in order for me to complete treatment. Patient care not affected.
Post-operative stage
Example 26. Patient came to the surgery with pericoronitis on lower right third molar and facial swelling. The patient was given a 1 x 3g amoxicillin sachet, which he took on the spot. We noticed he was allergic to penicillin, he rang his mother and she informed he once had swelling and rash when he was a child, no incidents since. The patient was informed of this and advised to go to emergencies. The staff rang NHS direct and could not advice on the situation. The patient stayed in the practice for about an hour and he showed no symptoms of allergy.

These are extracts from the free-text narrative descriptions of patient safety incidents reported to the National Reporting Learning System. The extracts have been edited by the author to correct typographical errors and remove indecipherable text.

Example 27. Patient attended the emergency clinic with a toothache. He was assessed and prescribed amoxicillin. The patient returned the following day as there wasn't any improvement with the pain. The dentist working that session noticed he had been prescribed amoxicillin but the patient was allergic. The dentist told the patient to stop taking the amoxicillin immediately and prescribed an alternative. The patient was happy with this. He had only taken one of the amoxicillin prescribed.

Example 28. A prescription was made out for Amoxicillin 500mg*21 and Metronidazole 200mg*21. The notes said patient was allergic to penicillin. The patient has a complex medical history. The dentist's concentration was on other aspects of the consultation. The dentist realised his prescribing error within a few minutes while writing up patient notes. Staff went out of building to see if patient still nearby. Patient does not have contact telephone numbers. Dentist immediately advised senior colleague and clinical director.

Example 29. Amoxicillin 250mg three times daily was prescribed to patient for an infected socket after asking whether she was allergic to penicillin. Patient called in approximately half an hour later saying that she has gone red in her face and is itchy on her legs advised to come back immediately. No stridor angioedema or wheezing, itching on her legs. Called GPs downstairs who agreed to see her immediately. Sent patient downstairs with a nurse and she was temporarily registered with the GP practice and was seen by one of the GPs. Called her in the afternoon to see how she was. Patient felt all right. Updated medical history regarding penicillin allergy.

Example 30. Dentist gave prescription form for 3g sachet. I dispensed 250mgs capsules. Dentist informed, asked me to contact the patient to return for correct antibiotics.

4.5. Chapter summary

In this chapter, I have employed a mixed-methods approach to analyse free-narrative descriptions of PSI-reports submitted to the NRLS related to primary care dentistry. In doing so I have characterised and identified the main PSIs, as well as their contributory factors and outcomes. To my knowledge, this is the first mixed-methods analysis of reports from primary care dentistry. The WHO's Safer Primary Care Expert Working Group encourages a better understanding of PSIs and their adverse outcomes, as well as the identification of priority areas.[3] In this chapter, as the vast majority of the reported incidents did not lead to harmful outcomes, priority areas based on their frequency in accordance with the clinical stages previously conceptualised in Chapter 3, have been identified. The most common reported incidents from primary care dentistry included: a) *delays in a treatment or procedure,* b) *procedural errors,* c) *medication-related adverse incidents,* d) *equipment failure and* e) *errors in obtaining or processing x-rays*. *Wrong-tooth extractions* were the incidents with the most harmful outcomes, although it should be noted that most reported incidents did not result in patient harm. As stated in Chapter 3, the field of patient safety research in dentistry has progressed without adopting standardised definitions,[206] therefore, in dentistry there is still no international agreement to distinguish between PSIs, contributory factors and outcomes. To take account for this lack of agreement, in this Chapter I firstly employed a mixed-methods exploratory sequential design that allowed me to systematically deconstruct the free-narrative descriptions in PSI-reports into quantitative data.[152, 153] I employed qualitative methods to develop the three coding frameworks that are shown in Appendices 8 to 10.

The qualitative methods employed in this study comprised a thematic analysis and the constant comparison of the emerging themes with existing patient safety classification systems. The development of these frameworks was also supported by the literature review in Chapter 1 and evidence base obtained from the systemic scoping review described in Chapter 3. There frameworks were then used by myself and a second coder (AS) to guide the systematic quantitative coding of the reports. The recruited second coder was previously trained and achieved very good agreement with a Cohen's Kappa statistic of 0.860 ($p<0.01$). This methodological approach has been used in other mixed-methods studies for analysing incident reports.[4, 128, 220, 221]

The reports I analysed are likely to constitute the tip of the iceberg[63] as they only included events that were actually reported. Since its introduction in 2003, the NRLS has collected over 15 million incident reports; however, less than 1% of NRLS reports originate from primary care.[222] Whilst NHS healthcare professionals might be aware of the NRLS, their fear of punishment from reporting incidents, the time required to report, and the lack of belief that reporting will lead to change, are all recognised barriers to submitting incident reports.[222] Moreover, a challenge I encountered was to bring sense to the data, as Renton and Sabbah[143] (2016) also reported. The data was largely made up of unstructured information with insufficient information about the demographics and disciplines involved. Such omissions limit a more in-depth understanding of the contexts in which the incidents occurred.

Although the majority of the incidents did not lead to harmful outcomes, a notable finding was that the majority of harmful outcomes were due to wrong-tooth extractions (48.1%; 37/77). As a result of this incident, 34 of the 37 patients (91.9%) required further unnecessary procedures. As these events can be prevented, the area of unnecessary procedures needs to further explored; paying particular attention to those events with the highest potential to cause severe harm. These events resonate with the area of NEs, which are entirely preventable high-impact events.[19] Therefore, in the following chapter, I will describe the process I employed to seek an expert-based consensus of a list of NEs for primary care dentistry through a formal international e-Delphi study. The findings from Chapter 3 and Chapter 4 were further used to support the third and final stage of my PhD programme (Chapter 5).

Chapter 5 . Developing agreement on never events in primary care dentistry: an international eDelphi study

5.1 Introduction

The findings from Chapter 3 and Chapter 4 have provided insights into the diversity of PSIs and adverse outcomes occurring in primary care dentistry. Based on their frequency, I identified key preoperative, intraoperative and postoperative areas for improvement. This included include: a) *delays in a treatment or procedure,* b) *procedural errors,* c) *medication-related adverse incidents,* d) *equipment failure,* and e) *errors in obtaining or processing x-rays*; however, it is important to point out that the majority of these PSIs did not lead to harmful outcomes. I also identified *wrong-tooth extractions* as another key area for improvement, an incident that was also identified as the main source of harmful outcomes. *Wrong-tooth extractions* are of interest within dentistry and patient safety due to their severity and high potential for prevention[186, 202, 205, 223, 224] and, in the UK, this incident meets the criteria for a NE.[19]

NEs are entirely preventable high-impact events, which are defined as serious, largely preventable PSIs that should not occur if the available preventive measures are implemented.[19] The criteria from the former NPSA for defining NEs is shown in Chapter 1 (see Table 1.5). However, as described in Chapter 3, patient safety research activity in primary care dentistry is mostly descriptive without standardised definitions and different methodological approaches. As a result, no systematic attempts have been made to identify and propose NEs for international use. Parallel to the development and implementation of the study described in this Chapter, Black and Bowie (2017) proposed an initial list of NEs for dentistry[145] (see Table 5.1). However, the authors also recommended a more systematic approach to review the literature and identify other potential NEs existing within primary care dentistry. The authors also suggested the need to address a more diverse composition of participants to be more representative of primary dental care settings.

Table 5.1 NEs for primary care dentistry proposed by Black and Bowie[141]

Black and Bowie (arranged by themes)
A. Checking medical history and prescribing
1. Failure to check past medical history
2. Incorrect prescribing
3. Extraction when INR not checked
4. Extraction when on intravenous bisphosphonates
B. Infection control and decontamination
5. Using dirty/unsterilised equipment
6. Reuse of single-use items.
7. Poor infection control
8. Not following correct hand hygiene procedures
9. Patient contracts a blood borne virus
C. Emergency drugs and equipment
10. Emergency drugs out of date
11. Equipment out of date
12. No up-to-date cardio pulmonary resuscitation training
13. Defibrillator defective or not being checked
D. Extracting or restoring the wrong tooth
14. Extracting wrong tooth
15. Restoring wrong tooth
16. Incorrect dental charting
E. Treating the wrong patient
17. Wrong record for the patient
18. Wrong patient invited into the surgery
19. Fitting the wrong lab work
F. Inhalation or ingestion of foreign objects or substance
20. Inhalation of, or swallowing, crown or instrument
21. Not using rubber dam
22. Hypochlorite incident
G. Record keeping and referrals
23. Forgetting to write up notes
24. Not including enough information in a patient note
25. No record of soft tissue examination
26. Failure to send a referral
27. Delay in sending a referral

This current chapter provides a description of the approach I followed in this thesis to integrate the findings described in Chapters 3 and 4, in order to generate a list of candidate NEs and to achieve international expert-consensus regarding a list of NEs for primary care dentistry.

5.2 Aim

- To develop and achieve consensus on a list of NEs through the responses from a panel of primary care dental experts located around the world.

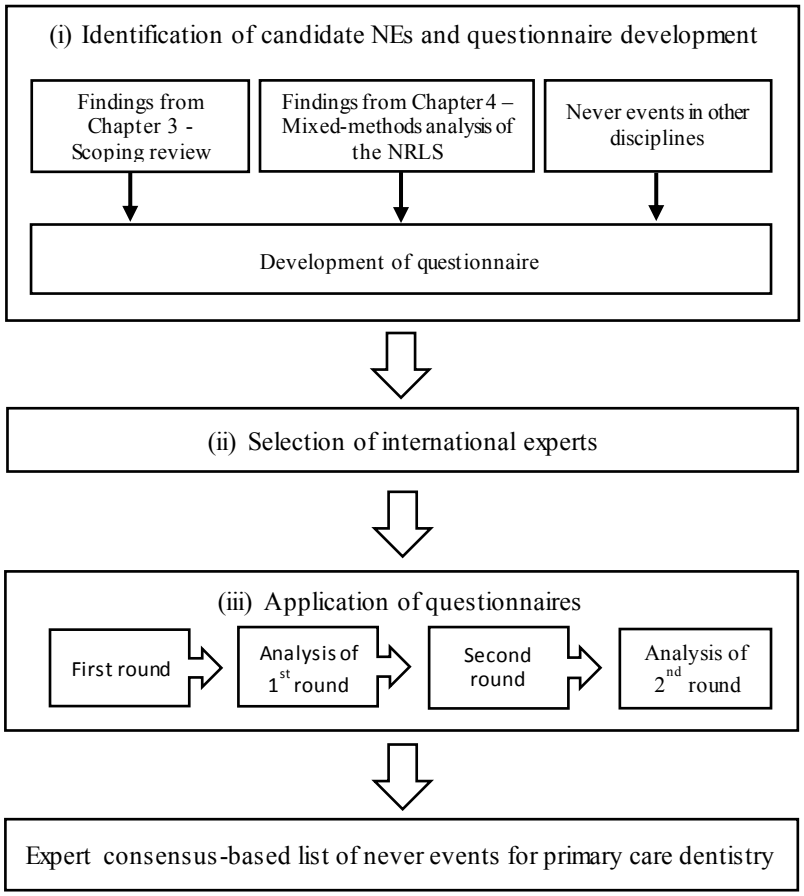
5.3 Objectives

- To identify an international panel of experts on patient safety in primary care dentistry
- To build a list of candidate NEs applicable to primary dental care settings
- To establish an international expert consensus-based list of NEs for primary care dentistry.

5.3 Methods

I undertook a modified electronic Delphi (eDelphi) exercise based on the method developed by the US Research and Development Corporation (RAND) in 1948.[225, 226] The first RAND experiment was conducted in 1951, but it was not made available to the public until 1962, as it was originally developed to forecast the impact of technology on warfare.[227] This method involves a formal, structured process for generating consensus among a group of experts based on feedback obtained from their anonymous responses.[228-230] Such an approach is favoured in cases where little to no empirical or historical data exist and therefore, an aggregated group response from experts is needed.[229, 231, 232] There were three stages to the study (see Figure 5.1): i) the identification of candidate NEs and questionnaire development; ii) selection of the experts; and, (iii) the iterative completion of a sequence of questionnaires by this panel of experts. The use of electronic questionnaires instead of paper-based questionnaires represented a modification to the originally described traditional Delphi process. I decided to use electronic questionnaires due to the convenience in contacting and recruiting panel members, as well as conducting the study with participants from different countries. This electronic approach has been previously used in other studies.[233, 234]

Figure 5.1 International expert consensus-based Delphi method



As shown in Table 5.2, my modified Delphi version consisted of using electronic questionnaires instead of paper-based questionnaires that in the past have been sent by traditional mail services.

Table 5.2 Comparison between the RAND method and the proposed modified version

Method	Questionnaire format	Anonymity	Iteration	Controlled feedback	Face-to-face contact	Statistical group response[a]	Stability of responses[b]
Classical (RAND version)	Paper-based	Yes	Yes	Yes	No	Yes	Yes
Modified version	Electronic	Yes	Yes	Yes	No	Yes	Yes

a. Expressed in medians
b. Variation of opinions around the median

5.3.1 Ethics

Ethical approval for the first (Appendix 15) and second (Appendix 16) round was obtained from the University of Edinburgh's Centre for Population Health Sciences Research Ethics Committee. (Ethics Application number 1624)

5.3.2 Stage 1: Identification of candidate never events and questionnaire development

As the Delphi method aims to make effective use of informed expert judgement,[232] the experts needed a synthesis of available empirical evidence.[225] Therefore, I used three approaches to identify the candidate NEs that were included in the initial questionnaire. The criteria shown in Chapter 1 (see Table 1.5) was used to define NEs.[19] First, I used the list of potential NEs that was developed during the systematic review described in Chapter 3 (Table 3.5). Then, additional candidate NEs were identified during the mixed-method analysis of PSI-reports, as described in Chapter 4. I reviewed these reports to assess whether they met the NE criteria according to the original NPSA definition (see Table 1.5 in Chapter 1). Finally, the third approach constituted the revision of existing lists of NEs in hospital care, lists which were developed by the NPSA[19] and NEs for general practice.[235] Table 5.3 shows the NEs that I considered, based on my clinical experience, to be transferable to dentistry.

Table 5.3 Revised list of never events from the Department of Health [19]

	Potential for transferrable to dentistry?
Wrong site surgery	Yes
Wrong implant/prosthesis	Yes
Retained object post-procedure	Yes
Mis-selection of a strong potassium-containing solution	No
Wrong route administration of medication	No
Overdose of insulin due to abbreviation or incorrect device	No
Overdose of methotrexate for non-cancer treatment	No
Mis-selection of high strength midazolam during conscious sedation	No
Failure to install functional collapsible shower or curtain rails	No
Falls from poorly restricted windows	No
Chest or neck entrapment in bedrails	No
Transfusion or transplantation of ABO-incompatible* blood components or organs	No
Mis-placed naso- or oro-gastric tubes	No
Scalding of patients	No

Note: ABO= Antibodies Blood Group

Based on these approaches, I developed an initial list of candidate NEs. As shown in Table 5.4, these were grouped into four clinical contexts. These were conceptualised

as i) the period that comprises any routine assessment or check-up, ii) the period before clinical treatments were carried out (pre-operative stage), iii) the period of clinical treatment (intra-operative stage), and iv) the period after the clinical treatment (post-operative stage).

Table 5.4 List of candidate never events for primary care dentistry

Routine assessment
Missed diagnosis of oral cancer[236]
Delayed referral of patients with clinical suspicion of cancer[235]
Pre-operative stage
Mistaken patient identity
Failure to prescribe antibiotic prophylaxis before treating root canal infections
Procedure carried out without voluntary and signed informed consent
Intra-operative stage
Use of non-sterile instruments or equipment
Use of dental material known to be allergic to the patient
Use of outdated material
Administration of unlabelled local anaesthetics
Injection of wrong anaesthetic solution[197]
Ingestion & aspiration of foreign objects[31, 34, 35, 47, 59, 62, 65, 85, 92, 97, 98, 105]
Wrong tooth treated or extracted[142, 180, 184, 186, 196, 197, 201, 205]
Severe apical tooth resorption due to orthodontic treatment[167]
Nerve damage due to errors in treatment plan [204]
Intravascular injection of local anaesthetic[176]
Acrylic set inside the mouth[189]
Jaw fracture due to implant placement[191]
Accidental injection of sodium hypochlorite[182]
Overdose of sedatives[189]
Needle stick injuries[235]
Post-operative stage
Retained foreign objects after surgical procedures[19]
Prescription of a drug to a patient with a known allergy
Prescription of teratogenic drug to patients known to be pregnant[235]

5.3.3 Stage 2: Selection of experts

In accordance with the original Delphi method, [225, 226] a sample of 15 experts is recommended.[225] Therefore, I identified a convenience sample of 41 potential participants to ensure a participation rate of at least 70% and to increase the stability of the responses. This sample included participants from different countries, levels of experience, academic backgrounds and specialties (e.g. general dentistry, paediatric dentistry, endodontics, oral surgery and public health) within primary dental care. Table 5.5 shows the criteria used for the identification and selection of experts. All

eligible experts received an invitation to participate (Appendix 17) by e-mail that included an information sheet and a consent form (Appendices 18 and 19). Participants were asked to read these documents and provide their voluntary signed consent before their participation.

Table 5.5 Criteria for the identification of experts

Criteria	Justification
More than three years of active clinical experience	Minimum time I assumed was required for experts to experience their own PSIs and ascertain which ones should be considered never events
More than three years of active academic experience	Minimum time I assumed was required for experts to observe patient safety incidents committed by students and ascertain which ones should be considered never events
Any experience in leadership roles within institutions or national dental associations	Potential advocates for patient safety in primary care dentistry
Any experience in patient safety at a clinical or organisational level	To assure that participants were familiar with patient safety as a discipline and their concepts

5.3.4 Stage 3: Iterative completion of a sequence of questionnaires

In the first round, I distributed e-mails containing the questionnaire including the definition of NEs and the instructions for answering each item (Appendix 20). Each item corresponded to a candidate NE and included three criteria which participants were asked to score. These were based on the criteria of 'preventability', 'severity' and and the criterion 'should be classified as never event' outlined by the Never Events Policy and Framework of the NHS (Table 1.5).[19] I removed the criterion surrounding 'the past and future risk' as my systematic scoping review identified evidence of 14 of the initial list of candidate NEs being reported over a period of 20 years.[206]

In accordance with the Delphi method,[237] participants were asked to assign a number between 1 to 5 in which the number five represented the closest proximity of each candidate NE to meet the NE criteria displayed in Table 1.5. Also, the experts were asked to provide reasons for their assigned scores and recommendations for any modification, addition or elimination of NEs on the list. The responses were collected, anonymised and summarised. Moreover, participants were asked to suggest any potential NE not included. A period of three weeks was given to complete and return

the questionnaire. The study was started on 11th September 2016. To achieve high response rates, three reminders were sent on the 7th, 12th and 19th day following initial contact. Non-responders were given an additional reminder on the 21st day.

For the second round, NEs were rephrased or discarded in line with the scores, comments and suggestions received in the first round (Appendix 21). Participants were provided with the group's median score for each item along with their responses (expressed in medians) and an anonymous summary of the comments received (Appendix 22). The respondents were asked to read this feedback and decide if their original scores should be changed. If they decided to modify them, they were asked to score the items on the same scale and provide a reason for changing their original score. Again, they were asked to provide reasons for their assigned scores and recommendations for modification of items, additions or elimination of NEs on the list. Participants then received a second and final anonymous summary of their comments (Appendix 23).

5.3.5 Analysis

After each round, all responses were collected and anonymised. Then, all the scores and comments were transcribed into a data collection tool using Microsoft Excel software.[162] According to the Delphi method, after each round, median scores are estimated per item.[226, 237] However, as participants were requested to assign scores in each of the three criteria for every candidate NE, I decided to summarise the overall score for each NE, together with the overall median scores of the three criteria for every candidate NE were calculated. The median of these final responses represented the group response.[237] Any unanswered field was considered as 'no opinion.' The retrieved comments were also summarised and were analysed for the refinement of the list of NEs, which was included in the second round. Contrasting comments were grouped and compared to assess the possible inclusion of additional items.

Percentages of agreement were assessed by grouping the overall median proportions of 'agree' and 'totally agree'. Proportions greater or equal to 80% were interpreted as satisfactory agreement. This procedure was repeated after each round until a consensus greater than, or equal to, 80% was achieved. Participants also received feedback from the final stage.

5.4 Results

A total of 41 experts were invited to participate in the study. Out of these, 32 agreed to participate and provided their informed consent and completed the first round questionnaire. No potential participant explicitly refused to take part in the study. Of the 32 participants who completed the first round, 29 went on to finish the second round. Reasons for not completing the second questionnaire included no replies after the third reminder was sent (n=2) and no response after further clarification was asked about the answers provided. The detailed demographics and professional features of the expert panel are shown in Table 5.6.

Table 5.6 Demographic and professional features of the Delphi expert panel

Expert No.	Gender	Country	Main Discipline	Academic	Clinical practitioner	Public health practitioner
1	Male	Argentina	Prosthodontics	✓	✓	✓
2	Male	Australia	Public health and community	✓		✓
3	Female	Brazil	Public health and community	✓		✓
4	Male	Cambodia	Paediatric dentistry	✓		
5	Female	Cambodia	Public health and community	✓		✓
6	Female	Chile	General dentistry	✓	✓	
7	Male	China	Public health and community	✓	✓	✓
8	Female	Colombia	Geriatric Dentistry	✓	✓	
9	Male	Colombia	Public health and community	✓		✓
10	Female	Indonesia	Public health and community	✓		✓
11	Male	Kenya	Orthodontics	✓	✓	
12	Male	Mexico	Periodontics	✓	✓	
13	Female	Mexico	Paediatric dentistry	✓	✓	
14	Female	Mexico	General dentistry	✓	✓	
15	Female	Mexico	Periodontics	✓	✓	
16	Female	Mexico	Paediatric dentistry	✓	✓	
17	Male	South Africa	Public health and community	✓	✓	✓
18	Female	Spain	General dentistry	✓		✓
19	Male	Spain	General dentistry	✓		✓
20	Female	Sudan	Public health and community	✓		✓
21	Male	Sudan	Paediatric dentistry		✓	
22	Female	Sudan	Oral and Maxillofacial surgery	✓	✓	
23	Female	Sudan	General dentistry	✓	✓	
24	Female	Sudan	Periodontics	✓	✓	
25	Female	UK	Sedation and Special Care Dentistry	✓		
26	Male	UK	Orthodontics	✓	✓	
27	Female	UK	Government Policy and Strategy Advisor			✓
28	Male	UK	General dentistry	✓	✓	
29	Female	UK	Sedation and Special Care Dentistry	✓	✓	
30	Male	UK	Sedation and Special Care Dentistry	✓	✓	
31	Female	UK	Prosthodontics	✓	✓	

Expert No.	Gender	Country	Main Discipline	Academic	Clinical practitioner	Public health practitioner
32	Female	USA	Public health and community		✓	✓

In brief, out of the 32 the participants, the majority were from UK (n=7), followed by Mexico and Sudan (n=5 each). There were two participants each from Cambodia, Colombia and Spain, and one participant each from the following countries: Argentina, Australia, Brazil, Chile, China, Indonesia, Kenya, South Africa and the US. Public Health and Community Dentistry were the main disciplines (n=9) represented, followed by General Dentistry (n=6), Paediatric Dentistry (n=4), Periodontics (n=3), Sedation and Special Care Dentistry (n=3), and Orthodontics (n=2). See Table 5.7 offers a full breakdown of disciplines represented. Concerning the professional roles, 16 participants had both academic and clinical roles whereas eight had professional roles in academia and public health. Only three participants had academic, clinical and public health roles.

5.4.1 First and second rounds

We formulated 24 candidate NEs, which were incorporated into the first questionnaire. No agreement was reached for any of the first 24 candidate NEs in the first round. The scores, comments and feedback received provided the basis for refining and expanding the initial list into 43 candidate NEs. After the second round, the consensus was achieved in 23 out of the 43 candidate NEs (See Table 5.7). These NEs related to routine assessment (n=3), pre-operative (n=3), intra-operative (n=13) and post-operative (n=4) stages of dental procedures. Examples of these included 'failure to register patient's history of allergies to medication' (routine assessment), 'failure to sterilise re-usable instruments' (pre-operative), 'wrong-tooth extractions' (intraoperative) and 'prescription of teratogenic drug to patients known to be pregnant.' Candidate NEs that did not reach consensus are shown in Table 5.8.

Table 5.7 Consensus on candidate never events after the second and final round

Candidate never events during…	Group median response	% of agreement*
… routine assessment		
Failure to register patient's history of allergies to medication	5	96.6
Failure to refer for oral cancer assessment after patient's lesion do not heal after two weeks of receiving treatment	5	93.1
Failure to implement oral cancer screening as part of the routine assessments	5	89.7
… **pre-operative stage**		
Treatment provided to the wrong patient	5	96.6
Failure to check patient´s identity before implementing a procedure	5	93.1
Failure to sterilise re-usable instruments	5	89.7
… intra-operative stage		
Wrong tooth extracted	5	96.6
Use of non-sterilised re-useable instruments	5	89.7
Patient's eye injured due to the omission of using appropriate eye protection	5	89.7
Administration of unlabelled cartridge of local anaesthetics	5	89.7
Jaw fracture during implant placement due to poor treatment plan	5	89.7
Jaw fracture during implant placement due to its incorrect placement	5	89.7
Injection of sodium hypochlorite into surrounding structures during root canal treatment/irrigation	5	89.7
Use of dental material in a patient with known history of allergy to the dental material used	5	89.7
Re-use of disposable items	5	86.2
Aspiration (inhalation) of foreign objects	5	86.2
Use of non-disinfected equipment	5	82.8
Re-use of damaged endodontic files	5	86.2
Injection of wrong anaesthetic solution	5	86.2
… post-operative stage		
Prescription of a drug to a patient with a known allergy to the drug	5	93.1
Prescription of teratogenic drug to patients known to be pregnant	5	93.1
Retained foreign objects after surgical procedures (excluding root canal procedures)	5	89.7
Incorrect medication prescribed to paediatric patients	5	89.7
*(agree + strongly agree)		

Table 5.8 Candidate never events that did not achieve consensus

Candidate never events during…	Group median response	% of agreement*
… pre-operative stage		
Failure to prescribe antibiotic prophylaxis before treating patients at risk of developing endocarditis	4	79.3
Surgical or complex procedure carried out without voluntary and signed informed consent	4	79.3
Failure to take pre-operative radiographs prior to invasive or surgical procedures	4	69.0
… intra-operative stage		
Extraction in a patient with a non-medically controlled bleeding disorder	5	79.3
Severe apical tooth resorption due to applying heavy forces during orthodontic treatment	4	79.3
Nerve damage due to errors in treatment plan	4	79.3
Treatment performed to a patient with a previously known untreated medical condition that can potentially be exacerbated by the dental treatment	5	75.9
Wrong tooth treated (excluding extraction)	4	75.9
Thermal injury to the pulp for not using irrigation during cavity/crown preparation	4	75.9
Overdose of sedatives	5	75.9
Needle stick injuries	4	75.9
Thermal injury to the soft tissues during root canal obturation with guttapercha[a]	4	69.0
Ingestion (swallowing) of foreign objects	4	65.5
Tooth extraction in a patient that received radiotherapy in the jaw or maxilla	4	65.5
Chemical injury by dental materials	4	65.5
Tooth extraction in a patient treated with bisphosphonates	4	62.1
Perforation of the maxillary sinus	4	62.1
Intravascular injection of local anaesthetic	4	62.1
Perforation of the tooth during root canal treatment	4	58.6
Acrylic set inside the mouth	3	48.3

*(agree + strongly agree)
**expressed as the median calculated from your three responses in every candidate never event
Agreement reached
[a]gutta-percha obturation is a technique used in endodontic treatments to fill the root canal system prevent microorganisms to re-enter it

5.5. Chapter summary

In this chapter, supported by the systematic scoping review in Chapter 3 and the mixed-methods analysis of PSI-reports in Chapter 4, an evidence base for developing an initial list of 43 candidate NEs is presented. From this list it was possible to achieve consensus on 23 NEs. They related to four distinct categorised: i) routine assessment (e.g., 'failure to register patient's history of allergies to medication'), as well as ii) pre-

operative (e.g., 'failure to sterilise re-usable instruments'), iii) intra-operative (e.g., 'wrong-tooth extractions') and iv) post-operative (e.g., 'prescription of teratogenic drug to patients known to be pregnant') stages of dental procedures.

The international expert consensus-based list of 23 NEs described in this Chapter, matches with 10 of the 27 NEs proposed by Black and Bowie (published after the completion of my study).[145] Although, I identified similar domains for NEs (e.g. drug prescription, wrong-tooth extractions, infection control practices, aspiration of foreign objects and treating the wrong patient), 13 of my proposed NEs did not match those proposed by Black and Bowie.[145] However, I believe I have addressed the methodological concerns also highlighted in the study by Black and Bowie.[145] I achieved this outcome by firstly developing an initial list of candidate NEs supported by the systematic scoping review[206] as described in Chapter 3. This list was further complemented by the mixed-methods analysis of PSI-reports described in Chapter 4, and the review of established NEs in general practice[235] and secondary care.[19] Secondly, I followed a structured and rigorous approach appropriately modified from processes developed by the RAND Corporation.[225, 226] Finally, I recruited an international panel of professionals with clinical and academic backgrounds, as well as experience in public health who provided different insights about NEs. However, in my sample of international experts, only three public health practitioners had an active role in researching and disseminating findings in patient safety research relevant to dentistry. Therefore, as more evidence accumulates and training and education in patient safety training increases, the number of patient-safety focused experts are likely to increase. I believe my proposed list shown in Table 5.8 should be further updated, based on the consensus of future patient safety experts who are working in the field of dentistry.

Having described my findings across the three stages of my PhD, I will now build an integrated discussion of my findings in each of the stages (Chapters 3 to 5) with the current literature (building on Chapter 1). Then, I will examine the contribution of my PhD to the evidence base of patient safety research in primary care dentistry.

Chapter 6 . Discussion and conclusions

6.1 Introduction

During the course of this PhD, I have broadened my understanding of patient safety and its role within primary care dentistry. I achieved this, as described in Chapter 1, beginning with an overview of the relevant global empirical literature on patient safety research and its related terminology with a particular focus on primary care and dentistry. This overview of the literature allowed me to develop my aims, objectives and overall structure of the PhD, which is described in Chapter 2. Then, as described in Chapter 3, I produced a systematic summary of empirical data on the state of current knowledge on patient safety research in dentistry. The findings from this systematic scoping review revealed that progress has been hampered through a lack of standardised definitions.[206] For example, there is still no international agreement to differentiate, in dentistry, between PSIs, contributory factors and outcomes. This lack of clarity cause me to reflect on the generalisation of the evidence generated for the past 20 years. However, the poor methodological consistency of the evidence also suggests important issues around the internal validity of the methods used. As Ioannidis pointed out: "*The greater the flexibility in designs, definitions, outcomes and analytical modes in a scientific field, the less likely the research findings are to be true*."[238] To ensure the internal validity of my findings, I used standardised terminology and developed three evidence-based coding frameworks to bring structure to studies described in Chapters 3 to 5 and to draw insights from the analysed data.

I also broadened my understanding of patient safety in primary care dentistry by identifying the main sources of unsafe care, their contributory factors and outcomes (described in Chapter 4). The most common PSIs reported from primary care dentistry included: i) *delays in treatment*, ii) *procedural errors*, iii) *medication-related adverse incidents*, iv) *equipment failure* and v) *errors in obtaining or processing x-rays*. *Wrong-tooth extractions* were the incidents with the most harmful outcomes.

Although most reported incidents did not result in patient harm, the findings described in Chapter 4 allowed me to reflect that these incidents should be prioritised for research and quality improvement, instead of only focusing on those incidents that lead to harm. I now understand that PSIs that do not result in harm are also important sources of

learning, as these are more frequent than harmful PSIs and offer insights into underlying systemic flaws. Finally, the findings described in Chapters 3 and 4 allowed me to build the evidence base to develop a list of candidate NEs. This list was further validated in Chapter 5 through an international consensus by a group of patient safety experts in primary dental care.

In this chapter, I seek to integrate the findings from the three stages of my PhD, in line with my introductory chapter and more recent developments in the patient safety literature. In doing so, I will explore the implications of my findings for policy and practice. Then, I reflect on the strengths and the limitations of the three phases of my PhD. I also offer some recommendations for future research.

6.2 Interpretation of findings in light of the existing literature

In the following sections of this chapter I discuss how my findings add to the gradually accruing evidence base of patient safety research in dentistry, as well as highlighting further opportunities for research and quality improvement. To achieve this outcome, I sought for similarities and contrasts of my findings with those reported in the existing literature, described in Chapter 1. My findings were also compared with emerging literature identified during the course of my PhD. In doing so, I further elaborated a discussion around the integration of my findings and propose recommendations for practice, policy and research.

6.2.1 Patient safety incidents

Primary care dentistry is a discipline which is mainly focused on intra-operative processes. This focus was consistent in my findings as the most frequently reported PSIs in the literature (Chapter 3) and the NRLS (see Table.4.4, Chapter 4) were intra-operative incidents. Having analysed the free-narrative descriptions of PSIs submitted to the NRLS, intra-operative incidents such as *procedural errors*, *medication-related adverse incidents*, *equipment failure, and errors in obtaining or processing x-rays* remained among the most frequent incidents regardless of clinical stage. After having explored the common underlying factors to these incidents, I found that *equipment failure* was both a PSI and a contributory incident. On the one hand, as a PSI, *equipment failure* was mainly related to lack of equipment maintenance and poor equipment design; on the other hand, I found *equipment failure* to be a shared

contributory incident between *procedural errors* and *errors in obtaining or processing x-rays*. The latter PSIs also shared *distraction* as a main contributory factor. However, I also found that among the main PSIs, their contributory incidents were not shared between each other. Contributory incidents for *procedural errors* also included *insufficient assessment*. Moreover, *medication-related adverse incidents* were mainly due to the patient's previous health-related conditions and/or non-compliance from the patient.

When I compared the distribution of the intra-operative incidents with the existing literature, I found similar proportions of incidents related to *inhalation and ingestion of foreign objects* (4%), *adverse reactions* (4%) and *wrong-tooth extractions* (2%), as reported by Thusu et al. (2012) who also analysed reports from the NRLS.[142] However, their study[142] was limited to describing single-incidents submitted over a period of one year (2009), whereas I analysed multiple-incident reports over a period of eight years, and further identified combinations of incidents and their reported contributory factors. My findings also showed that incidents related to *equipment failure* accounted for 6.2% of all incident types, and were also the third most common incident within the intra-operative stage (11.0%). This incident type has also been reported by Perea-Perez et al. and[201] Hiivala et al.[197, 239] Other previously reported incidents were *inhalation and ingestion of foreign objects* through the revision of relatively small samples of AE case reports,[240] malpractice cases,[201] and dental patient records.[140] *Wrong-tooth extractions* were identified as the main source of harmful incidents. Although not frequent (2.7%), these incidents have been studied previously[142, 143] as they meet the criteria of NEs, which should be entirely preventable high-impact incidents.[19]

Although my findings show that intra-operative incidents were predominant among the main PSIs (56.1%; 817/1,456), the distribution of PSIs per clinical stage differed by 8.4% when compared with the distribution reported by Thusu et al.[142](47.7%; 960/2,012). Probable reasons for these discrepancies are likely related to (1) the different NHS-coded filters used within to select the reports, (2) the different approaches to structuring and coding incidents, contributory factors and their outcomes and (3) the increase of incident reporting through the years due to increasing awareness of patient safety, also known as the 'rising tide phenomena'.[241] These

discrepancies also highlight misclassification issues for the measurement and identification of priorities for PS, in the absence of a standardised classification system for patient safety in primary care dentistry. Although most of my identified incidents occurred intraoperatively (56.1%; 817/1456), I also identified that preceding incidents or contributory factors such as *equipment failure*, *unexpected movement of the patient* and *lack of equipment maintenance* have a role among intra-operative incidents.

The most frequent **pre-operative incidents** I identified were *delays in treatment, incorrect or unavailable documentation* and *breaches of confidentiality*. Common specific contributory incidents and/or contributory factors between them were not found. My findings show that contributory incidents for *delays in treatment* were mostly flaws within administrative procedures (e.g. errors in managing appointments) whereas the contributory incidents for *incorrect or unavailable documentation* were IT-errors and inefficient transfer of information between healthcare settings. Contributory incidents for PSIs involving *breaches of confidentiality* as these were related to wrong medical records and errors from the staff (e.g. failure to adhere to procedures or regulations and distraction). However, when I compared the common underlying factors between the intra-and pre-operative incidents, I found that equipment-related events were also present as contributory factors (e.g. lack of equipment maintenance and lack of supplies) for patients experiencing *delays in treatment*. When compared with the literature, only Obadan et al.[240] (2015) had previously identified delays in treatment. Although I identified more detailed types of incidents, conceptual similarities are appreciated with the clerical errors (36%), management errors (4%) and communication errors (5%) identified by Thusu et al.[142] Diagnostic and communication errors between the dentist and the patient have also been reported by Hiivala et al.[197, 239]

Post-operative incidents were the least reported events.[206] Although I identified post-operative medication-related PSIs (e.g. prescription or dispensing), these accounted for 3.6% (52/1456) of all the reported incidents. Perea-Perez et al.[201] and Hiivala et al.[197, 239] have previously identified medication-related PSIs. However, PSIs related to prescription of medications, or their dispensing, remain largely unreported. A potential reason behind the insufficient reporting of medication related PSI may be explained

by a generalised assumption, as discussed in Chapter 1, that healthcare delivery in dentistry is safer than that which is delivered in secondary care. Therefore, any dental staff and patients are less likely to report incidents that resulted or could result in avoidable harm. Patient safety culture should therefore be fostered through the profession to encourage incident reporting.

6.2.2 Contributory incidents and contributory factors

According to the report from the Institute of Medicine (now the National Academy of Medicine),[16] the majority of medical errors are due to faulty systems and processes. Reason´s Swiss Cheese Model of System Accidents,[30] and the evidence-based Yorkshire Contributory Factors framework[55] for hospital settings, have been developed to demonstrate that human errors are often a consequence of latent organisational flaws, such as administrative or management issues. However, the findings described in my systematic scoping review (Chapter 3) suggest that the roles played by administrative and organisational factors in the occurrence of PSIs have scarcely been explored in primary care dentistry.[206] The limited body of evidence identified found that administrative errors,[142] equipment failure,[142, 197, 239] and errors for obtaining or processing x-rays[142] are the main causes of PSIs in primary care dentistry. Other contributory factors include patient factors (e.g. elderly patients, patients with disabilities), *staff factors* (e.g. distraction, fatigue and economising in the dental practice) and *organisational factors* (e.g. switching dentists, inadequately trained staff and insufficient post-treatment follow-up). [197, 239] However, these studies have mostly provided a general description of contributory factors.

In this PhD, I systematically reviewed the literature in Chapter 3 and built the evidence-base to further develop, in Chapter 4, empirical coding frameworks for PSIs and their contributory factors. I then assessed multiple incidents per report and structured these in chronological order from which I also obtained combinations of incidents. These combinations comprised of respective contributory incidents (which preceded primary incidents) and contributory factors (which influenced the occurrence of primary incidents).

When data were available, and regardless of the distribution per clinical stage, the *contributory incidents* for the main primary incidents were: a) the patients' inability to

access the dentist, b) equipment failure and c) errors in managing appointments. The main *contributory factors* for the main primary incidents were: a) distraction, b) insufficient staff members and c) lack of equipment maintenance. For the main harmful incident, which was wrong-tooth extraction, distraction from the dentist was identified as the main contributory factor. Although distraction has been reported in the literature,[143] i) inadequate checks, ii) incorrect radiographs, and iii) wrong diagnoses have also been reported as causes for wrong-tooth extraction.[143]

6.2.3 Outcomes

The overall characterisation of outcomes in Chapters 3 and 4 showed a clear distinction between local and systemic adverse outcomes. In Chapter 3, I conceptualised the term "systemic adverse outcomes" to include a variety of specific events that have been used in the literature to describe medical emergencies[142] and systemic complications.[240] These systemic adverse outcomes included allergic reactions (including anaphylaxis), *vasovagal responses*, *faint/loss of consciousness* and *seizures* and *dizziness*.[142, 197, 240] I also compared these outcomes with those I identified and characterised in Chapter 4 (see Appendix 10) and found similar systemic adverse outcomes. Although a variety of systemic outcomes was identified in Chapter 4, my findings also show that these outcomes were mainly a consequence of medication-related adverse incidents.

In Chapter 3, I conceptualised the term "local adverse outcomes" to include a variety of events that were described as injuries[142] including include lacerations, sharps, burns, nerve damage and damage to the temporomandibular joint[197, 201, 240] These local adverse outcomes were similar to those I identified and characterised in Chapter 4 in order to develop the framework of incident outcomes (see Appendix 10). Then, after coding the free narrative descriptions within the NRLS-reports, I identified lacerations/bleeding, chemical injuries and thermal injuries as the main local outcomes reported. In Chapter 3, my findings also showed that the majority of reported PSIs, noted in the literature over the past two decades are, mostly related to local and immediate adverse outcomes (see Table 3.4). From the retrieved articles, it appears that the main concern for reporting these in the literature is the severity of harm. [166, 170, 172, 174, 178, 180, 183, 184, 190, 193, 196, 201] Malpractice studies were the main source for the

identification of adverse outcomes in my systematic scoping review.[206] Cases included in such studies might involve incidents where the harm was severe enough to raise sufficient concern for patients to seek legal and financial compensation.[28, 242] Therefore, as the field of patient safety grows within dentistry, the quality and thus contents within all available patient safety data sources for research, also need to be improved. To achieve this improvement, further studies should not be limited to only reporting severe harm incidents, but should also report near misses and/or no harm incidents.

The adverse outcomes I identified in Chapter 3 may constitute the tip of the iceberg as near-misses and less severe AEs are often unreported,[63] my systematic scoping review showed gaps about the relation to PSIs leading to less severe harm or no harm. As described in Chapter 4, the majority of outcomes resulted in either no harm or low harm (94.7%; 1,379/1,1456). As shown in Table 4.8, the frequency of these outcomes is higher than harmful incidents. Near misses and no harm incidents can be analysed for the identification of risk and hazards[58] without waiting for enough harmful incidents to accumulate and be analysed. Therefore, in Chapter 4 I expanded the characterisation of adverse outcomes and also included other organisational and non-harmful outcomes within the identified no harm incidents. In doing so, I compared my findings in Chapters 3 and 4. This comparison showed that, although local and systemic adverse outcomes were identified, only lacerations/bleeding (99/1,420; 6.8%) were among the most commonly described outcomes. Other non-adverse outcomes such as the increased documentation/follow-up (12.4%; 181/1,456), delays in using the dental clinic (5.8%; 85/1,456), unnecessary x-ray exposure (5.1%; 74/1,456) and repeated procedures/additional treatment (4.9%; 71/1,456) were more frequent than other local and systemic adverse outcomes. Although these outcomes did not result in harm, their identification showed the presence of flaws in the provision of efficient and effective primary dental care, which represent dimensions for quality improvement, as proposed by the IOM[32] (see Table 1.2 in Chapter 1). Moreover, the over-utilisation of healthcare services can a) contribute to future unnecessary harm, b) result in additional financial demands for the patient and c) cause waste of resources within the healthcare system.[243]In Chapter 3, I also identified other non-immediate adverse outcomes (see Table 3.4) such as *nerve damage*, [166, 170, 174, 183, 184, 190, 192, 196, 200,

[201] *post-treatment infection*,[170,174,175,178,180,184,185,189,190,197,201] *prolonged pain*[172,180,184,196] and *temporomandibular complications*,[184,190,196,201] all of which can take weeks or months to be detected following treatment. Although *temporomandibular joint complications* were also reported within the NRLS, these and other non-immediate adverse outcomes represent a challenge to be associated with any traceable potential contributory factors. To address this challenge, standardised and updated dental records are required to screen any potential PSIs and outcomes that might occur in the course of the patient's treatment. However, this strategy should also include a follow up and registration of any potential non-immediate adverse outcomes. Kalenderian et al.[198] have shown the potential of a trigger tool adapted for dentistry to identify adverse outcomes located within electronic health records. In their study, the authors employed information about 'incision and drainage' and 'multiple visits' to identify cases of infection, temporomandibular joint complications and tooth fractures.[198]

6.2.4 Never events

In Chapter 5, I achieved international expert consensus in 23 out of 43 candidate NEs (See Table 5.8), as well as matching with 10 of the 27 NEs proposed by Black and Bowie (published after the completion of my study).[145] Although not exact, I identified similar domains for NEs (e.g. drug prescription, wrong-tooth extractions, infection control practices, aspiration of foreign objects and treating the wrong patient). However, I also found discrepancies since 13 of my proposed NEs did not match those identified by Black and Bowie.[145] Of the 17 remaining NEs, five of them were similar to candidate NEs used during the first and second round of my study. These were: a) mistaken patient identity, b) wrong-tooth treated (excluding extraction), c) tooth extraction in patients treated with bisphosphonates, d) use of outdated material and e) ingestion of foreign objects. However, these were not included in my list as I did not achieve consensus equal or greater than 80%. Probable reasons for discrepancies, regarding the the rest of the 12 NEs that did not match my list, are the process for identification of candidate NEs and the composition of experts. Black and Bowie[145] initially conducted a rapid literature review and then held workshops with dental practitioners. My list, however, was developed and structured in accordance with the conceptualised stages in my systematic scoping review[206] described in Chapter 3. Black and Bowie[145] identified a sample of experts in Scotland whereas my sample of experts

had a more heterogeneous and international composition. Moreover, the feedback I received from the experts, during the first and second rounds, highlighted that recommendations, guidelines and availability of clinical/environmental resources were likely to be different between countries. This feedback suggests that, although similar concerns around NEs are shared, the presence of different resources between countries, for the provision of quality dental care provided the experts with a different knowledge-base and experience. These differences highlight the need to standardise guidelines and recommendations for clinical procedures, which need to be shared between countries. However, the differing clinical resources also highlight that countries are likely to have own contextually appropriate local patient safety concerns. Therefore, the possibility of establishing agreement on country-specific lists of NEs should also be explored.

6.3 Literature update

In the course of my PhD, I periodically reviewed and updated the literature. In doing so, I broadened my view and therefore my understanding of patient safety and how its research and developments have been constructed around primary care dentistry over time.

6.3.1 Continuous efforts to reinforce patient safety

The WHO and other national bodies have continued their efforts to encourage healthcare providers and regulatory bodies to continuously improve the quality of care. Previous, scarcely explored areas such as under-utilisation[244] and over-utilisation[245] of services, as well as patient safety in primary care,[117, 246] are also now receiving attention. The global extent of under-utilisation of healthcare services has been recently explored.[244] In their study, Glasziou et al. reported that under-utilisation of care is an issue prevalent in both high- and low-income economies. Factors contributing to this issue broadly are: a) inaccessible healthcare services to the patient, b) the unavailability of effective services, for instance the result of a lack of resources, c) the clinician's failure to provide effective care, and d) the patients' (inadequate) compliance and adherence to effective healthcare interventions.[244] When I compared these factors with my findings, I found that issues of accessibility to the dentist and unavailability of effective services were also present in my data. These issues were

mainly related, as a contributory incident or a contributory factor, to patients experiencing delays in receiving treatment, which was the main PSI reported within the NRLS data. Therefore, these findings reveal that under-utilisation of services primary dental care services is also a prevalent issue in patient safety.

The global extent of over-utilisation of healthcare services has also been explored. In their study, Brownlee et al [245] reported that, although over-utilisation is a recognised problem globally, its significance has not been clearly defined. In this article, the authors highlighted the over-utilisation of medications, screening tests, diagnostic tests and therapeutic procedures as areas in which overuse has the potential to affect patients and/or healthcare systems. When I compared these factors with my findings, I found that repeated procedures/additional treatments and unnecessary x-ray exposures were among the more frequent reported outcomes. These outcomes were even more frequent that other local or systemic adverse outcomes. Therefore, these findings reveal that over-utilisation of services in primary dental care is also an issue that can be easily overlooked by researchers, policy makers and members of the dental profession. This point is also reflected in the focus of patient safety research when reporting harmful outcomes, described in Chapter 3.

Following the *Safer Primary Care* report,[3] the WHO released their technical series to provide member states with a common body of evidence around key issues in primary care for building national capacity in designing and delivering safe healthcare delivery. These technical series broadly include patient engagement[247] and education, in addition to training the healthcare workforce,[248] including human factors.[249] Other areas covered in these technical series are the process-related issues in healthcare delivery, such as administrative errors,[250] diagnostic errors,[251] medication errors,[252] multiborbidity[253] and transitions of care.[254] Guidance for the use of information and communication technologies in health,[255] also known as eHealth, is also available. In addition to these technical series, the WHO released the third global challenge toward the reduction of severe, avoidable medication-related harm by 50% in the following 5 years.[256]

In the US, 15 years after the publication of *To Err is Human* brought worldwide attention to patient safety,[16] the NPSF (now part of the IHI) convened an expert panel

to discuss the current state of patient safety. As a result, the report *Free from Harm* was released to reinforce the importance of patient safety, as the subject remains to be an important public health issue.[246] This report also reinforces the need for more focus on previously under recognised aspects of patient safety in primary care, such as overuse and underuse of treatments, misdiagnosis and complications of care.[246]

6.3.2 Progress within the UK

In the UK, 16 years after the publication of *An Organisation with a Memory*,[17] the NHS's Imperial Patient Safety Translational Research Centre issued the *Patient Safety 2030* report[117] and the *NRLS Research and Development* report[222] to reinforce the need for patient safety across the healthcare system. On the one hand, the *Patient Safety 2030* report[117] this report acknowledged the issue of patient safety as a shared goal throughout healthcare systems worldwide, stressing the point that it is not a matter which should be limited to high-income economies.[117] This report also recommended that international collaboration should focus, over the next 30 years, on the identification of common patient safety issues, including the measurement of a core set of high-level trends.[117] These trends are: a) the increasing complexity of cases and multi-morbidities as the population gets older by living longer, b) the reduction or limitation of resources as the demand for care increases, c) the increasing sophisticated solutions in care and d) the rise of antimicrobial resistance.[117] On the other hand, the *NRLS Research and Development* report[222] highlighted the need for the existing NRLS to be improved and that they should be integrated with other existing incidents. This need for the integration of reporting systems resonates with the need highlighted by Renton et al.,[257] also for an integrated approach to the reporting PSIs in dentistry. In their article, the authors highlighted that the wide variety of reporting systems can bring complexity and confusion to report incidents. The consequences of this complexity have been reported by Renton et al.[143] after they reviewed serious events and NE reports relevant to dentistry in the NRLS and STEIS databases. In their study, the reports were found to be incorrectly coded, were missing information and, in some cases, were duplicated within the same database.[143] The *NRLS Research and Development* report[222] also highlights the need to employ better IT approaches in order

to simplify incident reporting and to analyse the vast amount of accumulated reports. As the reports contain unstructured narratives of the PSIs, natural language processing (NLP) has emerged as an important area within patient safety research. NLP offers a set of informatics tools capable of transforming text into a structured format that can be used for research.[258] Extraction systems, based on NLP, have been developed in the medical domain,[259] however, these systems have not yet been introduced in dentistry. Following the *Patient Safety 2030*[117] and *NRLS Research and Development*[222] reports, NHS England announced the development of the Patient Safety Incident Management System (PSIMS), as the successor of the existing NRLS.[260]

6.3.3 Increasing awareness of, and attention to, patient safety in dentistry

As described in Chapter 3, the field of patient safety in primary dental care has been poorly organised for the past 20 years. Fortunately, in the course of my PhD, I discovered more organised efforts to address unsafe dental care practices have started to emerge. At an international level, the FDI has recently released three policy statements to be adopted by its country members. The first policy highlights the imperative for quality in dentistry,[261] which promotes the inclusion of competencies on quality as part of the full range of dental education and training, as well as the implementation of quality improvement practices. The second policy statement concerns the responsibility of dentists to implement evidence-based practices,[262] which encourage: a) the incorporation of the principles of evidence-based dentistry (EBD) in the dental curriculum, and also in continuing professional education and b) use the BD approach to help dentists interpret and apply the best available evidence in everyday practice. Finally, the third policy statement encourages country members to raise awareness among dentists and staff members about the risks of using non-compliant dental products with regulatory agencies.[263]

In the UK, in December 2015, the England's Regulation of Dental Services Programme Board released *The Future of Dental Service Regulation* report.[264] This document highlighted the absence of a clear model of regulation, with no clear definition of roles and responsibilities between organisations resulting in a confusing system, which can lead to duplication of efforts and inefficiencies within the system. Moreover, the report highlights the absence of a common data set focusing on quality

and safety that would enable regulators to establish overall safety of dental services across England. However, the report also highlights opportunities for improvement, including support for quality improvement.

Then, in 2016 the corporate strategy report: *Patients, Professionals, Partners, Performance* report was released by the GDC.[265] In this document, the GDC described their 2016-2019 plan for improving the regulation of dentistry/dental practices. This plan seeks to improve four main areas: a) patient-centred system, b) continuous support to dental professionals in delivering good quality dental care, c) effective regulation of dentistry and complaint procedures and d) efficient, effective and innovative regulation in line with the standards set by the Professional Standards Authority.[265] Then, in the same year, the GDC also released the *Shifting the balance: a better, fairer system of dental regulation* report,[266] which mentions that a "*good regulation should be focused first and foremost in learning*". Moreover, this report included specific proposals for actions, which broadly required the GDC to improve the standards for the dental team, as well initiating improvements within the education and continuous professional development of the dentistry profession. Therefore, this approach that focuses on learning, aligns with the purpose of the NRLS and the data I analysed, which represents an important source of learning and improvement in primary dental care.

The field of patient safety research in dentistry has also started to generate more robust findings via standardised methods and terminology. Recent studies oriented towards patient safety in primary care dentistry have focused on the characterisation of PSIs and AEs. Maramaldi et al.[267] published a primary classification of AEs based on feedback from dental professionals and domain experts obtained through focus groups and interviews. Then, over the course of one year, this preliminary classification of AEs was further refined by Kalenderian et al.[268] This classification system of AEs shares similarities with the systemic and local outcomes I identified in Chapter 4. However, my characterisation of outcomes was not limited to adverse outcomes as I expanded the characterisation of harmful outcomes and included no-harm outcomes, such as non-clinical outcomes in patients and organisational outcomes. Another contribution to the evidence base was provided by Hiivala et al.,[239] whose research

also characterised PSIs and assessed multiple contributory factors. However, their study was limited to report frequencies of these factors and did not explore the chronological sequence of those leading to the main incident. When compared with my findings, I also identified multiple incidents; however, I employed the Recursive Model for incident Analysis[216] to identify the chronological sequence of PSIs with their respective contributory incidents and contributory factors (see Appendixes 12 to 14).

6.4 Implications for policy and practice

Policy. Following *To Err is Human*, national PSI reporting systems were proposed to enable national-level learning about PSIs. In the UK, the NRLS in England and Wales has generated many lessons to improve patient safety. Examples in secondary care include the patient safety alerts for the risk of inadvertently cutting in-line (closed) suction catheters[269] and the risk of using different airway humidification devices simultaneously.[270] However, patient safety in dentistry is still in its early development and needs a clear patient safety-focused agenda. I believe the more frequent and harmful incidents described in Chapter 4 and the proposed list of NEs in Chapter 5 of this thesis can be used to inform administrators, dental associations and policymakers about the need for the development of interventions and policies. This initiative should be done at a national level by taking into consideration how dentistry is organised and financed within each country. In the UK, my findings can be used to inform the GDC's *Patients, Professionals, Partners, Performance* strategy[265] and the Revised Never Events Policy and Framework.[87] Data from incident reporting systems need to be part of a continuous quality improvement agenda set within those countries. The WHO's *Safer Primary Care* report [38] highlights many areas for research and development; my thesis adds new insights which warrant consideration to update the agenda which should now include dentistry.[141, 271] The Council of European Dentists has already recommended use of incident reporting systems in dentistry,[141] and these should now be either developed exclusively for the profession, or integrated into existing reporting systems for healthcare, such as the NRLS. Advocates supporting these reporting systems by specialty are also needed[4] and dentistry is no exception.

Any dentistry-focused initiative needs to be supported by clear regulations and policies that allow private and healthcare-funded dental practices to report all incidents, preferably to a single system. Currently, as Renton and Master highlighted,[257] multiple regulations by, for example, the GDC, the CQC and NHS England towards incident reporting by dentists in the UK, create complexity and unclear processes for dentists to follow. Parallel to the development of PSIMS, national policies for patient safety assurance within independent and NHS funded primary dental care services need to be either adapted from existing policies for medicine or developed in their own right. Such policies should include the use of standardised concepts of PSI and AEs, including clearly defined serious incidents and NEs for dentistry. The WHO's International Classification for Patient Safety,[29] and more recently the Minimal Information Model for Patient Safety, provide a common vocabulary for reporting and learning from PSIs.[272] Policies for the standardised reporting of PSIs should be implemented across the profession, combined with ensuring appropriate clinical governance to monitor and learn from PSIs, near misses and their outcomes.

The concept of 'never event' was first introduced by Kizer in 2001 to describe the 'most egregious health care errors' that shouldn't ever occur.[273] However, definitions for NEs vary between countries[274] and therefore making comparisons between countries is therefore challenging. [275] In the UK, Renton and Sabbah[143] have even reported discrepancies between the reports from two databases for cases of wrong-tooth extractions. These reports were also largely unstructured and were missing information about demographics, outcomes and learning points. Therefore, patient safety organisations, policy makers and dentistry communities need to: a) establish standards for the accuracy of NEs derived from administrative data and b) agree on a standard definition of a NE. [274] I believe my proposed list of NEs is a sound starting point for operationalising NEs to improve safety in practice, as well as facilitating further integration into existing reporting systems, such as the NRLS or PSIMS in the UK. Then, policies like the Framework for the Identification and Management of Never Events[87, 88] from the NHS should be either developed or adapted for dentistry, to be supported by education and training efforts, as well as clear policies for no-blame reporting or disciplinary actions.[53]

Practice. Initiatives to improve quality, including patient safety, in primary care dentistry should focus on improving the main sources of unsafe care. My research highlights consistent issues reported over the past eight years mainly in the intra-operative stage during which contributory incidents and contributory factors were mostly identified in the pre-operative stage. Therefore, I recommend improving the pre-clinical processes to reduce delays affecting patients receiving treatments or procedures by improving the communication between staff members and practices. Failures in communication and teamwork are one of the main issues in primary care delivery.[22] From a system-based perspective, policies should be developed to create an infrastructure at a national level to build and maintain professional networks and services to enable professionals to communicate and learn from each other.[248] Effective primary care teams, health information technology, effective transitions of care, effective diagnostic services and patient engagement are opportunities for patient safety improvement in primary care.[249]

I also recommend efforts to enable standardisation of intra-operative procedures. Many treatments or procedures in dentistry do not follow established evidence-based guidelines.[148] Therefore, these guidelines should be developed for further implementation and evaluation by national regulatory bodies supported by the law with agreed standards for performance.[276] Examples of these regulatory bodies within the UK include the Professionals Standards Authority[98] which oversees independent regulatory bodies such as the GMC[99] and the GDC.[100] These regulatory agencies, in their areas of interest, set the standards of competence and conduct that healthcare professionals must meet to obtain and maintain their registration and fitness to practice. One additional function of such agencies is to review the content and quality of education and training courses. Pre-service and in-service education relating to patient safety needs to be discipline-oriented in accordance with a system-based perspective to facilitate its sustainable improvement.[248] Other measures to tackle patient safety include the inspections undertaken by the CQC[78] and the NCAS for poorly performing dentists, doctors and pharmacists [102] Another strategy learned from the human factors research undertaken in hospital-based studies is to reduce the reliance on memory, attention or perception.[105] Examples of this strategy include

patient safety checklists for oral surgery,[277] endodontic procedures,[278] wrong-tooth extractions[223] and dental implant placement.[279]

Although the effectiveness of these checklists has not yet been tested in dentistry,[26] implementation could have a significant impact on prevention of wrong-tooth extractions. These have been classified as a "never events" due to both their severity and their high degree of preventability.[143, 280] I also recommend the periodic maintenance of all dental equipment, since faulty equipment was the fourth most common reported incident in my analysis. Moreover, it was also identified as a contributory factor for procedural errors and errors for obtaining or processing x-rays. Regardless of the type of incident or outcome, the integration of patient safety principles and concepts into the daily practice of clinicians and leaders is a necessary step to reduce all types PSIs and their adverse outcomes.[281] My recommendations also resonate with the 11 recently proposed basic practices/procedures by Perea et al.[282] (2015) for patient safety in dentistry. These broadly encourage: i) improvement in the areas of patient safety culture, ii) quality of medical records, iii) infection control practices, iv) medication prescribing, v) avoidance of unnecessary x-ray exposure and vi) usage of procedural checklists. However, a likely difficulty exists around how to most effectively foster an environment receptive to change.[283] Facilitators for a patient safety culture include the recognition of the risks of oral healthcare delivery through all health sectors and dental associations, as well as the integration of patient safety into the curricula of dental schools and within the organisational structure of dentistry.[151] The WHO's patient safety curriculum guides have outlined the core learning requirements for healthcare professionals.[121, 122] Online courses such as those provided by the Institute for Healthcare Improvement Open School,[284-286] are also valuable resources to help dental schools to integrate patient safety education into the professional curricula in dentistry.

6.5 Reflection on strengths and limitations

To reflect on the strengths and limitations of the studies conducted in my doctoral research, I have to highlight my previous experience as a clinical practitioner in primary care dentistry and additional training in Health Sciences (Master in Sciences).

I consider my previous experience as both a strength and a limitation that influenced my judgements about the methodological approaches described in this thesis.

Strengths. My background can be viewed as a strength, as I familiar with primary care dentistry as a discipline and the related clinical procedures. This previous understanding was reflected in the conceptualisation, data collection, interpretation and analysis of the information retrieved in the systematic scoping review, described in Chapter 3. These processes were further reinforced by employing published guidelines.[154, 155] The systematic scoping review method provided a comprehensive overview of the published empirical evidence on patient safety research in the field of primary care dentistry. I used a broad search strategy to retrieve as many potential articles as possible. Taking into consideration that quality assessment is not a component of scoping reviews,[163] the anticipated wide variety of studies allowed me to cover a broad range of relevant literature for analysis. Although patient safety research in primary care dentistry lacks a standardised terminology, I employed my clinical experience supported by internationally agreed terminology developed for patient safety research in hospital medicine. In doing so, I grouped the emerging AEs and PSIs into the major concepts shown in Figure 3.3. Then, I conceptually mapped and organised the PSIs and AE that were reported (see Tables 3.3 and 3.3). These steps provided the overall evidence-based structure I followed to understand PSIs (Chapter 4) and used to build consensus on my list of NEs (Chapter 5). The experience of submitting the manuscript of the systematic scoping review for publication, and responding to peer-reviewed comments, advanced my understanding of the method I employed in Chapter 3. This experience also allowed me to raise my awareness on improving the methodological approaches described in Chapters 4 and 5.

It is also important to highlight that the study described in Chapter 4 builds on a wider NHS-funded project, "*Characterising the nature of primary care patient safety incident reports in England and Wales: mixed methods study*", which was hosted at Cardiff University with The University of Edinburgh as a collaborator in this work. Thanks to this support, I held continuous discussions with colleagues at Cardiff University which helped me to bring more structure to the study, as described in Chapter 4. Having obtained an evidence-based conceptual structure in Chapter 3, I

discussed this structure with my supervisors and colleagues at Cardiff University. This process resulted in the agreement to employ a mixed-methods approach to systematically deconstruct the narratives present in the PSI reports into quantitative data.[152, 153] In conducting this method, I demonstrated the consistency of code application of primary PSIs by recruiting a second coder and achieving very good agreement with a Cohen's kappa statistic of 0.860 ($p<0.01$). This mixed-methods approach, at a conceptual level, mirrors the sequence of incidents described in the Swiss Cheese Model of System Accidents proposed by Reason,[30] that was discussed in Chapter 1. Moreover, this method has been used in other studies[208-210, 220, 221] and has received positive reviews.[287] To my knowledge, the study described in Chapter 4 is the first mixed-methods analysis of reports from primary care dentistry.

Finally, I used the findings from Chapter 3 and 4 to build the evidence base and generate a list of candidate NEs. I used this list to seek, in Chapter 5, an international experts' consensus-based list of NEs. In doing so, I have addressed the methodological concerns highlighted in the study by Black and Bowie.[145] Firstly by developing an initial NE-list supported by a comprehensive and systematic scoping review[206] (described in Chapter 3) complemented by a mixed methods review of patient safety reports from primary dental care in a national PSI reporting system (described in Chapter 4). The review also included established NEs in general practice[235] and secondary care. [19] Secondly, I followed a structured and rigorous approach appropriately modified from processes developed by the RAND Corporation. [225, 226] Finally, I recruited an international sample of professionals with clinical and academic backgrounds, as well as experience in public health services, who provided different insights of NEs. As a result I obtained a consensus from a more diverse composition of participants and thus, information that was more representative of, and relevant to, primary care dentistry.

Limitations. The heterogeneity of evidence retrieved in Chapter 3 posed challenges for the interpretation of the extracted data. Individually, the gathered data from each article was generated for specific and narrow objectives, which represented a challenge for data extraction and for the conceptual mapping and organising of the PSIs and AEs. To address this issue, I employed my clinical experience and internationally agreed

terminology to initially extract data about the emerging AEs and PSIs, which were later grouped into the major concepts shown in Figure 3.3. These concepts were also synthesised[164] and integrated in Tables 3.3 and 3.3. In doing so, I focussed on extracting data from particular incidents that I believed matched my experience and terminology, whilst potentially neglecting other incidents. I therefore acknowledge that my conceptual framework (Figure 3.3) might be incomplete. Therefore, in the future, I believe this systematic review will require an update to: a) develop a more comprehensive search strategy with free-text terms such as 'dental practice', 'negligence', 'non-compliance', 'primary dental care' or 'ambulatory dentistry' to other potentially missed incidents, b) employ a second reviewer with a professional background in dentistry, c) include studies from more recent years and d) revise the conceptual framework. Patient safety in dentistry is an emerging field and, as a consequence, there was insufficient evidence to either justify a systematic review, meta-analysis or to calculate pooled estimates. Nevertheless, the findings from the systematic scoping review revealed valuable information that allowed me to build the initial conceptual structure of this thesis.

One of the issues encountered in Chapter 4 was the quality of the incident reports submitted to the NRLS. The pilot analysis of 300 reports revealed that the free narrative descriptions, a mandatory field, constituted the only field which consistently contained data for coding and analysis. Renton and Sabbah (2016) also reported this data issue; it was largely unstructured data with insufficient information about the demographics and disciplines involved.[143] In my study, the absence of this information represented a challenge to bring sense to the data. In addition, the free narrative descriptions were often shorthanded and contained abbreviations or other jargon to describe clinical procedures. My strategy to deal with this issue was firstly by employing my experience as a dental practitioner to bring meaning to these abbreviations. Secondly, I re-read the narratives and annotated these abbreviations and searched their meaning through on-line medical- or dentistry-related search engines.

During the coding process, there was a risk of confirmation bias.[288] In the context of the study, as described in Chapter 4, this risk was related to the tendency to read the narrative descriptions and use my clinical experience to assign codes and confirm my

pre-existing hypotheses. Similarly, recognition bias was possible in the light of potential limitations of the vocabulary employed within the codes, which can result in limitations when attempting to clarify the complexity of what was described.[288] My strategy to deal with these difficulties consisted of the systematic application of codes in accordance with the Recursive Model of Incident Analysis.[216] This approach was also supported by discussions held with my supervisors and colleagues at the Cardiff University, which drew upon their previous experiences in analysing data from the NRLS. These recommendations consisted of assigning codes which represented what was explicitly described in the reports; inferences were to avoided, in particular when no explicit description was available. This strategy allowed me to minimise the subjectivity in the coding process.

The PSI reports submitted to the NRLS are likely to constitute the tip of the iceberg[63] as these only included events that were actually reported. Also, these reports are limited to NHS-funded practices in England and Wales. Therefore, reports NHS-funded practices in Scotland were included and analysed in the study described in Chapter 5. Although, I assume that similar types and frequencies of PSIs are likely to happen within independent and/or private primary dental care practices, these still need to be explored. Since its introduction in 2003, the NRLS has collected over 15 million incident reports; however, less than 1% of NRLS reports originate from primary care.[222] Whilst NHS healthcare professionals might be aware of the NRLS, a recent evaluation of the NRLS showed that fear of punishment from reporting incidents, the time required to report, and the lack of belief that reporting will bring any improvement are reasons for under-reporting.[222]

Patient safety in primary care dentistry remains largely unexplored and is a relatively new field of dentistry. In Chapter 5, I achieved international consensus on a list of NEs; however, in my sample of experts, only three public health practitioners had an active role in researching and disseminating findings in patient safety research relevant to dentistry. Therefore, as more evidence accumulates and training and education in patient safety training increases, the number of patient-safety focused experts is likely to increase. I believe my proposed list should be further updated based on the

consensus of future patient-safety-experts' opinions and the evidence emerging from primary care dentistry.

6.6 Recommendations for further research

Further research of patient safety in primary care dentistry should now more closely align with the research agenda for WHO's Safer Primary Care Programme.[3, 22] This agenda includes: a) recognising that risks to patients exist during the delivery of primary care dentistry,[3] b) the identification of priority areas and key knowledge gaps, [3] and c) the improvement of data collection methods and improved taxonomies in order to generate learning from PSIs.[22] The findings described in Chapter 4, permit one lens to focus on apparent priority issues for improvement and is a starting point for setting patient safety research priorities in dentistry,[283] particularly towards prevention, policy making and resource allocation for interventions. The priority areas I identified were *delays in treatment, procedural errors, medication-related adverse incidents, equipment failure, errors in obtaining or processing x-rays* and *wrong tooth extractions*. I believe these areas should be pursued with research strategies that embrace robust primary research designs and methods with agreed working definitions.[20] Examples of these research designs include cross-sectional studies using secondary data (e.g. medical records, malpractice cases) or mixed-methods when the available data consists of unstructured narrative descriptions. Moreover, NLP also provides an oportunity to link the field of informatics with patient safety research, as NLP can help to develop informatic tools to analyise free narratives and transform them into a structured format that can be used for research.

Given that patient safety research aims to minimise risks of future PSIs, contributory factors should also form the basis of understanding where and how to intervene in systems to mitigate or prevent future similar incidents. I believe my coding frameworks (Appendices 8 to 10) provide a basis for further research, as well as an understanding of the relationships between incident types and contributory factors which highlight opportunities to improve patient safety. Further research in this area also bring the opportunity to corroborate my findings, including the coding frameworks, with other sources of patient safety data. Lastly, as the field of patient safety makes advances in dentistry, my list of NEs (see Table 5.8) should be further

updated and amended as more evidence accumulates and more professionals are trained in patient safety. This improvement of the list would require an update of the systematic scoping review (described in Chapter 3), as discussed previously, to include other potentially missed incidents and to include studies from more recent years.

6.7 Conclusions

In this PhD, I aimed to describe, understand PSIs and build consensus on a list of NEs in primary care dentistry. To achieve this aim I compiled the first comprehensive account of empirical evidence on the types and frequencies of PSIs and AEs arising from primary care dentistry. The findings from this work, described in Chapter 3, show that patient safety in dentistry has not progressed at the same pace as it has in hospital care. Therefore, future research must embrace robust primary research designs and methods with agreed working definitions.[20] Furthermore, consideration should be given to which frameworks already developed in medicine [30,35] might beneficially be adapted to suit dentistry.

Other research included in my thesis is the first mixed-methods analysis of PSI reports from primary care dentistry submitted to the NRLS, details of which are presented in Chapter 4. By employing this methodological approach, I have developed coding frameworks for the classification of PSIs, contributory factors and outcomes (Appendices 8 to 10). These frameworks can be taken into consideration for the development of a classification system which maximises learning from reports describing PSIs and their outcomes in other patient safety studies in dentistry.[4, 134, 220] Further, I identified priority areas for research and policy making which were related to delays in a *treatment or procedure, procedural errors, medication-related adverse incidents, equipment failure, errors in obtaining or processing x-rays* and *wrong-tooth extractions*. Other initiatives for research and improvement in clinical practice should also focus on improving the administrative processes to reduce delays in treatment and the standardisation of procedures. The integration of patient safety in the professional curricula is also needed to reduce *procedural errors and errors in obtaining or processing x-rays*. As more patient safety-focused evidence continues to emerge, such material should be considered for integration into evidence-based guidelines. Compliance with these guidelines can also be encouraged by fostering a patient safety

culture in dentistry. Failure of equipment is another area for improvement, which could probably by achieved by encouraging periodic maintenance and checking the availability of appropriate supplies. Lastly, I have produced the first international expert consensus-based list of NEs for primary care dentistry.

The findings described in this thesis provide a starting point to support future research initiatives, quality assessment and governance activities. These findings can be used by dental regulators, as well as professional and academic communities in dentistry to foster patient safety through evidence-based initiatives that can be translated into action. Future areas for research include the further refinement and standardisation of a patient safety classification system for dentistry. As priority areas may differ between settings and countries, these areas should also be explored in different scenarios. This will require the analysis of PSIs and their outcomes in different sources of data, which then can be corroborated with my findings. I also believe that my coding frameworks provide a basis for coding other data that also contain free narrative descriptions. Likewise, NLP offers a set of informatics tools capable of transforming text into a structured format that can be used for research.[258] Data extraction systems based on NLP have been developed in the medical domain.[259] However, this innovation has yet to be explored in dentistry. Patient safety is an emerging field in dentistry that offers a wide spectrum of opportunities for both research and improvement. Although beginnings can be challenging, dentistry has the support of two decades of evidence from secondary care. This support can help dentistry to advance the field of patient safety at a quicker pace than with secondary care.

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Appendix 1. List of preferred terminology and definitions.

Concept	Definition
Active error	An error that occurs at the level of the frontline operator and whose effects are felt almost immediately.[16, 29]
Adverse event	An injury that was caused by medical management or complication instead of the underlying disease and that resulted in prolonged hospitalisation or disability at the time of discharge from medical care or both.[29]
Classification	An arrangement of concepts into classes and their subdivisions to express the semantic relationships between them.[29]
Clinical error	The failure to carry out a planned action as intended or the application of an incorrect plan.[30]
Contributory factor	An antecedent factor to an event, effect, result or outcome similar to a cause. A contributory factor may represent an active failure or a reason an active failure occurred, such as a situational factor or a latent condition that played a role in the genesis of the outcome.[29]
Degree of harm	The severity and duration of harm, and the treatment implications, that results from an incident.[29]
Error	The failure of a planned action to be completed as intended or use of a wrong, inappropriate, or incorrect plan to achieve an aim.[29]
Error of commission	An error that occurs as a result of an action taken.[289]
Error of omission	An error that occurs as a result of an action not taken.[289]
Harm	Impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering and death.[29]
Healthcare	Services received by individuals or communities to promote, maintain, monitor or restore health.[29]
Healthcare associated harm	Harm arising from or associated with plans or actions taken during the provision of health care rather than an underlying disease or injury.[29]
Knowledge-based error	The conscious application of existing knowledge to the management of novel situations.[29, 290]

Concept	Definition
Lapse	Errors which result from some failure in the execution and/or storage stage of an action sequence, largely involving failures of memory, that do not necessarily manifest themselves in actual behaviour and may be only apparent to the person who experience them.[29]
Latent error	A defect in the design, organization, training or maintenance in a system that leads to operator errors and whose effects are typically delayed or lay dormant in the system for lengthy periods of time.[29]
Near miss	An incident which did not reach the patient.[29]
Never events	Serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented.[19]
No harm event	When an error does not result in an adverse event for the patient and the absence of injury is owed to chance. This differs from a near miss, in which injury is absent because the error was "caught". [20]
Patient safety	the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.[29]
Patient safety incident	An event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.[29]
Preventable adverse event	Adverse event that would not have occurred if the patient had received ordinary standards of care appropriate for the time.[29]
Quality of care	The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.[20]
Slips	any observable, external failure in the physical execution of a plan and generally as a result from deficits in attention or perception.[42]
Skill-based error	A mistake that] relates to problems for which the person possesses some pre-packaged solution, acquired as a result of training, experience, or the availability of appropriate procedures.[291]
Violation	Deliberate deviation from an operating procedure, standard or rules.[44]

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17.2 Thereshall be no right whatsoever for any third party to enforce the terms andconditions of this Agreement. The Parties hereby expressly wish to exclude theoperation of the Contracts (Rights of Third Parties) Act 1999 and any otherlegislation which has this effect and is binding on this agreement.

17.3 Tothe fullest extent permitted by law, this Licence will be governed by the lawsof England and shall be governed and construed in accordance with the laws of England. Any action arising out of or relating to this agreement shall be brought in courtssituated in England save where it is necessary for BMJ Group for enforcement tobring proceedings to bring an action in an alternative jurisdiction.

Appendix 4. Overview of search databases

Medline.

Medline is a database from the U.S. National Library of Medicine (NLM) that comprises records from 1946 to date. The publications registered cover scientific journals, newspapers, magazines and newsletters in the areas of biomedicine and health (including dentistry). This database is indexed with NLM Medical Subject Headings (MeSH) which were used for the search strategy.

Embase.

Embase is a database containing records from 1947 to the present. It includes research literature on drug adverse events as well as conference abstracts from conferences (from 2009), research done on medical and drug safety and systematic reviews. This database is indexed with the Elsevier Life Science thesaurus Emtree.

Cochrane library.

The Cochrane Library is composed from six databases a collection of six databases including a database for systematic reviews, the Cochrane Central Register of Controlled Trials (CENTRAL), the Cochrane Methodology Register, the Database of Abstracts of Reviews of Effects (DARE),the Health Technology Assessment Database and the NHS Economic Evaluation Database (EED).

The Scientific Electronic Library Online (Scielo).

Scielo is a database originated in Brazil that contains online journal publications and scientific journals in open access. Also serves a model for cooperation between developing countries for electronic publishing.

Virtual health library (VHL).

VHL is an online library of sources from the Pan American Health Organization (PAHO) developed by the Latin American and Caribbean Center on Health Science

Information (BIREME). Latin American and Caribbean countries contribute to this on-line collection of health information database including over 1,000 institutions in more than 30 countries. This database has also access to Scielo.

Global health library (GHL).

GHL is a database launched by the WHO in 2005 in order to foster and facilitate access, particularly to developing countries, to reliable sources of scientific information on health sciences. Moreover, through BIREME, the GHL has access to the VHL network and therefore to Scielo

Appendix 5. Search strategy (MEDLINE)

1. exp Dentistry/
2. dentistry.mp.
3. exp Diagnostic errors/
4. exp Medical errors/
5. exp Medication errors/
6. exp Delayed diagnosis/
7. delayed diagnosis.mp.
8. misdiagnosis.mp.
9. treatment delay*.mp.
10. exp Unnecessary Procedures/
11. exp Patient Safety/
12. exp Risk Management/
13. adverse event*.mp.
14. exp Patient Harm/
15. patient harm.mp.
16. exp Malpractice/
17. exp Accidents/
18. exp Iatrogenic Disease/
19. exp Needles/ae [Adverse effects]
20. exp Surgery, Oral/
21. dental complication*.mp.
22. systematic review*.mp.
23. "Review Literature as Topic"/
24. exp Research Design/
25. exp Research Report/
26. exp Clinical Trials as Topic/ or exp Adult/ or exp Epidemiologic Methods/ or exp Research Design/ or study design.mp.
27. exp Cross-Sectional Studies/
28. exp Intervention Studies/
29. exp Comparative study/
30. exp Follow-up Studies/

31. exp Prospective Studies/

32. exp Observational Study/

33. exp Cohort Studies/

34. exp Congresses as Topic/ or meeting abstract*.mp.

35. exp Meta-Analysis/

36. qualitative stud*.mp.

37. Ethnographic Research/

38. Phenomenological Research/

39. Models, Theoretical/ or Grounded Theory.mp.

40. focus group*.mp. or Focus Groups/

41. Interview/ or interview*.mp.

42. 1 or 2

43. 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21

44. 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41

45. 42 and 43 and 44

46. limit 45 to (human and medline and yr="1994 -Current")

Appendix 6. Data extraction form for systematic scoping review

General information		
Author(s)		
Year of publication		
Country		
Discipline(s)		
Provision of a working definition	Yes/No	
Explicit theoretical framework	Yes/No	
Research design		
Method for collecting data		
Measurement methods		
Study population		
Randomisation of sample	Yes/No	
Setting		
Main Type of procedure		
Patient safety incidents		
Lack of skill or experience of operators	Yes/No	Reported frequency(ies)
Errors in documentation or medical records	Yes/No	Reported frequency(ies)
Error related to clinical examination / diagnosis	Yes/No	Reported frequency(ies)
Administrative errors	Yes/No	Reported frequency(ies)
Communication errors	Yes/No	Reported frequency(ies)
lack of Informed consent	Yes/No	Reported frequency(ies)
Referral errors	Yes/No	Reported frequency(ies)
Failure to provide treatment	Yes/No	Reported frequency(ies)
Errors in treatment planning	Yes/No	Reported frequency(ies)
Multiple exposure to x-rays	Yes/No	Reported frequency(ies)
Equipment failure	Yes/No	Reported frequency(ies)
Procedural errors	Yes/No	Reported frequency(ies)
Broken instruments	Yes/No	Reported frequency(ies)
Local anaesthesia overdose	Yes/No	Reported frequency(ies)
Failure to appropriately treat medically compromised patients	Yes/No	Reported frequency(ies)
Inhaled & ingested objects	Yes/No	Reported frequency(ies)
Errors in sedation dosage	Yes/No	Reported frequency(ies)
Cognitive failure / action lapse/ confusion	Yes/No	Reported frequency(ies)
Negligence	Yes/No	Reported frequency(ies)
Infection control	Yes/No	Reported frequency(ies)
Wrong tooth	Yes/No	Reported frequency(ies)
Wrong treatment /procedure	Yes/No	Reported frequency(ies)

Wrong body part	Yes/No	Reported frequency(ies)
Drug prescription errors	Yes/No	Reported frequency(ies)
Lack of follow-up	Yes/No	Reported frequency(ies)
Local adverse outcomes	Yes/No	Reported frequency(ies)
Damage to anatomical site (injuries)	Yes/No	Reported frequency(ies)
Accidental injection of sodium hypochlorite	Yes/No	Reported frequency(ies)
tooth damage	Yes/No	Reported frequency(ies)
Treatment failure	Yes/No	Reported frequency(ies)
Alveolar bone loss	Yes/No	Reported frequency(ies)
Apical root resorption	Yes/No	Reported frequency(ies)
Alveolitis/dry socket	Yes/No	Reported frequency(ies)
Tooth loss	Yes/No	Reported frequency(ies)
Infection after treatment	Yes/No	Reported frequency(ies)
Poor healing	Yes/No	Reported frequency(ies)
Peri-implantitis	Yes/No	Reported frequency(ies)
Maxillary sinus perforation	Yes/No	Reported frequency(ies)
Tooth fracture after treatment	Yes/No	Reported frequency(ies)
Bisphosphonate-induced osteonecrosis of the jaw	Yes/No	Reported frequency(ies)
Occlusion or TMJ complication after treatment	Yes/No	Reported frequency(ies)
Nerve prolonged paraesthesia/ permanent impairment	Yes/No	Reported frequency(ies)
Prolonged pain Post-procedural pain/persistent	Yes/No	Reported frequency(ies)
Prolonged treatment/additional treatment	Yes/No	Reported frequency(ies)
Systemic adverse outcomes	Yes/No	Reported frequency(ies)
Adverse reactions (drug reaction ald LA)	Yes/No	Reported frequency(ies)
Medical emergencies	Yes/No	Reported frequency(ies)
Cardiovascular event (stroke or infarction)	Yes/No	Reported frequency(ies)
Diabetic events	Yes/No	Reported frequency(ies)
Hypoglycaemia (including coma)	Yes/No	Reported frequency(ies)
Angina pectoris	Yes/No	Reported frequency(ies)
Hypotension	Yes/No	Reported frequency(ies)
Vasovagal collapse /syncope	Yes/No	Reported frequency(ies)
Dizziness, Headache, Nausea or vomiting	Yes/No	Reported frequency(ies)
Asthma or apnea events	Yes/No	Reported frequency(ies)
Hyperventilation	Yes/No	Reported frequency(ies)
Brain damage	Yes/No	Reported frequency(ies)
Death	Yes/No	Reported frequency(ies)
Desaturation	Yes/No	Reported frequency(ies)
Prolonged sedation	Yes/No	Reported frequency(ies)
Allergic reaction	Yes/No	Reported frequency(ies)

Fits/Seisures	Yes/No	Reported frequency(ies)

Appendix 7. Level 1 Ethics approval

THE UNIVERSITY of EDINBURGH

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19 April 2016

Mr Eduardo Ensaldo Carrasco

Dear Eduardo

Re: Iatrogenic Harm in Dentistry

This is to confirm that the Level 1 Ethics Self-Audit undertaken by you with respect to the above study (as submitted on **15/04/2016**) demonstrates that the proposed research poses no reasonably foreseeable ethical risks. Within our research governance process, this means that the research proposed (as outlined on the Level 1 form) does not require formal ethical review by the Review Group – i.e. it can be considered to be 'exempt'.

You may forward this letter to any collaborating data owner who requires reassurance as to ethical oversight of the research proposed, together with the Level 1 form completed.

Yours sincerely

Diane White

Diane White
Ethics Review Group Administrator

Appendix 8. Patient safety incident framework

Types of incidents	Working definitions
Pre-operative stage	
1. Administration incidents	
Ability to access the dentist	Patient is not capable of approaching the dentist or dental care setting for receiving oral healthcare
Errors in managing appointments	Flaws in scheduling appointment for receiving oral healthcare
Errors in the logistics for transporting patients	Flaws in the transportation of patients from their residences to the primary dental care setting
Interpreter services not available or non-attendance	Absence of a translator to enable communication between the patient and any member of primary dental care team
Information filled incorrectly	Patient's information is not accurate
Errors in the process of payment systems	Errors in the process of healthcare payment systems
Failure to follow-up	Failure to monitor patient's treatment between appointments or after the treatment has finished
Delays in treatment	Failure in the provision of dental care or treatment when needed
2. Diagnosis and assessment incidents	
Errors in choosing the correct process or procedure	Failure in deciding the appropriate oral healthcare procedure or treatment
Insufficient assessment in history /examination	Failure in the provision of satisfactory or complete preoperative clinical evaluation
Delayed assessment	Preoperative assessment of the patients was postponed
Delayed diagnosis	The correct diagnosis was postponed
Missed diagnosis	Failure in achieving the correct diagnosis of a patient's condition
3. Documentation incidents	
Incorrect or unavailable documentation	Flaws in obtaining access and correct documentation of the patient
Record not up to date or information missing	Patient's medical records contain non-updated information or are incomplete
Inaccurate information on record	Patient's information in the medical record is not accurate
Wrong medical record	Flaws in obtaining or getting access to the correct medical record
4. Communication incidents	
Breaches of confidentiality	Personal details of the patient were mistakenly shared/exposed with/to other patients or unauthorised personnel
Incomplete referral	The patient's appropriate referral to other dentist or service was not completed
Communication errors between professionals	Failure to transmit and understand any information among healthcare professionals
Communication errors between dentist and patient	Failure to transmit and understand any information between the dentist and the patient
Delayed referral	The patient's appropriate referral to other dentist or service was not achieved on time
Inefficient transfer of information between healthcare settings	Failure to transmit or transfer the patient's information at an office level
Communication errors between staff and patients	Failure to transmit and understand any information between the staff members (excluding dentist) and the patient
Errors in obtaining the informed consent	Flaws in obtaining the patient's informed consent before the clinical treatment
Unnecessary referral	Inappropriate referral of patients
5. Insufficient supplies	Unavailability of supplies for appropriate actions/procedures in the preoperative clinical stage of a treatment
6. Dental laboratory errors	Flaws related any dental prosthetics or appliances developed by the dental laboratory
7. Professionalism issue	Errors in the professional conduct of healthcare professionals
8. Inaccurate laboratory test results	Errors in the process of receiving the accurate laboratory results

Types of incidents	Working definitions
Intra-operative stage	
7. Procedural incidents	
Procedural error	Procedural error for conducting the appropriate process or procedure
Medication-related adverse incidents	A detrimental patient condition that arises subsequent the intraoperative administration of medication (e.g. local anaesthesia, sedation, general anaesthesia)
Broken instrument	The breakage of any dental instrument during the conduction of the dental process or procedure
Errors in obtaining or processing x-rays	Flaws in the process for obtaining or processing x-rays
Procedure performed on wrong anatomical side or site	Any reported incident involving procedures performed on the wrong anatomical side or tooth
Ingestion/inhalation of foreign body	Accidental ingestion or inhalation of foreign bodies during the conduction of the dental process or procedure
Non-specified procedural complication	Detrimental of the patient's condition that arises during the conduction of the dental process or procedure that cannot be attributed to medication or allergies
Errors in the process of administering a medication	Errors in the process of administering medication to a patient
Errors in obtaining a biopsy	Errors in the process of obtaining a biopsy sample
Wrong instrument used	Any reported incidents in which an incorrect instrument was used in the correct process or procedure
Contraindicated dental material used	Incorrect dental material was used in the correct process or procedure
8. Equipment and supply related incidents	
Equipment failure	Faulty equipment during a process or dental procedure
Lost equipment	The location of the appropriate equipment is unknown when needed to conduct a process or dental procedure
Supplies out of date	Unavailability of appropriate up to date supplies
Equipment not available	Unavailability of the appropriate equipment when needed to conduct a process or dental procedure
9. Failure to comply with infection control standard procedures	Flaws from any staff member to follow/apply standard infection control practices
10. IT related incidents	
IT - Software errors	Errors within the software in any equipment used
IT - User errors	Errors from any staff member to use any device used
11 Other	
Unexpected movement of the patient	Unexpected and non-intentional movements from the patient during the process of care delivery
Unexpected movement from staff	Unexpected and non-intentional movements from any staff member during the process of care delivery
Post-operative	
12. Medication incidents	
Errors in the process of delivering a medication	Errors in the process of delivering a medication order or inappropriate medication order
Contraindicated medication prescribed/dispensed	A contraindicated medication was prescribed or dispensed
Wrong dose prescribed	Errors in the prescription of the correct dose of medication
Wrong medication prescribed	Errors in the prescription of the correct medication
Medication not available	The appropriate medication was not available
No medication/treatment given when appropriate	Errors in providing medication-treatment on time
Medication incorrectly stored	Flaws in the storage of medications
Lost prescription	The location of a medication prescription is unknown when needed
Unintentional drug overdose (self-administered)	A non-intentional overdose of an appropriately prescribed medication occurred
Wrong medication/treatment given	Failure to provide the correct medication

Appendix 9. Contributory factors framework

Types of contributory incidents	Working definitions
1. Staff factors	
Distraction	Inattention from the dentist which is thought to have influenced/contributed to a patient safety incident
Failure to adhere to procedures or regulations	Dentist or staff member did not comply with procedural clinical standards or regulations
Inadequate skills/knowledge	Dentist or staff member did not meet the expected set of skills or knowledge to implement a clinical procedure
Thinking error - action as planned but decision was wrong	The dentist or staff member failed in the decision-making process to determine the appropriate clinical course of action
No assistance from staff	Staff members did not assist the dentist during a clinical procedure
2. Equipment & supplies related	
Lack of equipment maintenance	The appropriate dental equipment does not work properly during a process or dental procedure
Poor equipment design	Flaws in the equipment or devices for conducting dental clinical procedures
Lack of supplies	Appropriate dental supplies to conduct a process or dental procedure are not available when needed
Equipment failure	Dental equipment fails to work or function appropriately during a process or dental procedure
3. Organization factors	
Insufficient staff members	Sufficient number of staff members were not available for conducting any clinical procedure
Inadequate or unavailable policies or guidelines to follow	Appropriate policies or guidelines were inadequate or not available for conducting the appropriate clinical procedure
Interpreter services unavailable	Interpreter was not available to enable appropriate communication between the dentist or staff member with a non-English-speaking patient
Failure to provide continuity of care to healthcare professionals	Failure to provide or assure, at an office level, the appropriate transition of care between primary dental care professionals or other healthcare professionals
Busy or overloaded dental practice	The dental practice is overloaded with patients waiting for receiving treatment
Cultural factors between dental team members	Individual patterns behaviour of any staff member (including dentist) influence the organizational approach to healthcare delivery
Insufficient education/training	Any staff member's performance was not supported with appropriate academic or clinical training
Long wait service	Patients experience greater waiting times than the average or expected waiting time
4. Patient factors	
Patient's previous health related conditions	Any history of a previous and underlying health related conditions of the patient (excluding allergy)
Unexpected movement of the patient	Any circumstance or moment in which the patient unintentionally move during the process of receiving oral healthcare treatment
Patient's previous history of allergies	Any history of a previous and underlying allergy-related health condition
Non-compliance from the patient	Any circumstance or moment in which the patient does not follow advice or instructions
Gag reflex	Any involuntary defence mechanism from the patient to protect the pharynx and throat from foreign objects during clinical care delivery
Patient unable to communicate in English	Any circumstance or moment in which the patient cannot communicate in English
Patient's pregnancy	Patient's pregnancy at the moment of receiving dental care
5. Dental laboratory errors	Flaws related any dental prosthetics or appliances developed by the dental laboratory

Appendix 10. Incident outcomes framework

Types of outcomes	Working definitions
1. Inconvenience to patient (non-clinical)	
Unnecessary x-ray exposure	X-ray related procedures are over utilised
Unnecessary procedures	Dental procedures (excluding x-rays) are over utilised
Repeated procedures / additional treatment	Flaws in the initial treatment resulted in additional procedures or treatment
Hospital admission	Patient safety incident that led to hospital admission
2. Local outcomes	
Laceration/bleeding	A deep cut or tear in skin or oral soft issues due to procedural patient safety incidents Bleeding of external or internal soft tissues of the oral cavity
Localised non-specified injury	Unspecified injury to any soft or hard tissue structures of the oral cavity due to procedural patient safety incidents
Localised pain/discomfort	A highly unpleasant physical sensation caused by procedural patient safety incidents.
Thermal injury	Unintentional application of heat to the external or internal oral soft tissues by dental material or equipment during any clinical treatment
Chemical injury	Injury due to the unintentional exposure of the oral soft tissues to dental materials (e.g. etching gel, sodium hypochlorite and peroxides)
Extended paraesthesia	Affection of the facial, maxillary or mandibular nerve branches involving numbness after receiving any dental treatment.
Bruises	Outcome/ injury reported as such or describing marks on unbroken skin and darker in color, as a result of dental care
Fracture	Outcome/ injury reported as such or describing mandibular fracture or maxillary fracture
Skin tear	Outcome/ injury reported as such or describing traumatic injuries to the external or internal oral soft tissues as a result of shearing or friction by dental instruments or devices
Needle-stick injuries	Outcome/ injury caused by needles (e.g. during local anaesthesia administration) that unintentionally punctured the external or internal oral soft tissues
Localised Post treatment infection/abscess	Outcome/ injury reported as such or describing the collection of pus within the teeth, gums or surrounding bone structure following a dental treatment (e.g. root canal treatment, surgical procedures)
Necrosis of soft-tissues	Outcome/ injury reported as such or describing irreversible degeneration of structural elements of the tooth (e.g. gum, bone, interdental papillae)
Localised swelling	Outcome reported as such or describing abnormal protuberance or localised enlargement following dental treatment
Affection of the temporomandibular joint	Outcome reported as such or describing the alteration of the masticatory function following dental treatment
3. Systemic outcomes	
Faint / loss of consciousness	The patient experienced weakness, dizziness and/or close to losing consciousness during or after a dental procedure
Vasovagal response	The patient experienced a slowed-down heart beat and overall weakness during or after a dental procedure
Seizure	The patient experienced a sudden epileptic episode during or after a dental procedure
Dizziness	The patient experienced disorientation or unsteadiness during or after a dental procedure
Anaphylaxis	Acute allergic reaction to a dental material or medication
Difficulty to breathe	The patient experienced difficulties for breathing properly during or after a dental procedure
Prolonged sleep / unarousable after sedation	The patient was reported unarousable or with prolonging sleep after a clinical procedure under sedation
Cardio-respiratory arrest	The patient experienced loss of consciousness and abnormal or absent breathing during or after a dental procedure
Redness	The patient experienced skin redness during or after receiving dental treatment
Deterioration / progression of condition	The patient experienced a deterioration of their overall health status during or after receiving dental treatment
Rash	The patient experienced a change in colour, appearance or texture of their skin

Types of outcomes	Working definitions
Nausea/vomiting	The patient experienced a sudden feeling or action of vomiting
4. Organisational inconvenience	
Delays in using the dental clinic	The dental staff is unable to use the dental practice for dental care delivery within the appropriate time frame
Treating patients without sufficient information	The patient received dental care without the sufficient information about the patient's condition or health status before conducting the clinical procedure
Increased documentation / follow-up	Increased documentation and/or follow-up due to flaws (including patient safety incidents) within the delivery of dental care
Legal implication	Any circumstance or moment that resulted in patient's seeking legal assistance
5. Psychological / emotional distress	Unintentional infliction of the emotional/psychological well-being of the patient due to patient safety incidents during or after the delivery of dental care
6. Death	Any reported death during or after receiving dental treatment

Appendix 11. Nine rules of the Australian Recursive Model of Incident Analysis

Recursive Model Incident Analysis Rules
1. An incident has a set of contributory factors and / or contributory incidents
2. An incident can contribute to another incident
3. Contributory factors cannot be incidents in their own right
4. An incident has a set of outcomes
5. An incident can be an outcome of another incident
6. Some outcomes cannot be incidents in their own right
7. An outcome of an incident could be a contributory incident to another incident
8. An incident can be designated the primary incident type – the incident proximal to the descriptive patient outcome
9. The outcome of a primary incident cannot be an incident

Appendix 12. Distribution of combinations in the pre-operative stage

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Delays in treatment	Ability to access the dentist	0	Insufficient staff members	0	0	77
Delays in treatment	Errors in managing appointments	0	0	0	0	31
Incorrect or unavailable documentation	0	0	Primary incident	0	0	30
Delays in treatment	0	0	Insufficient staff members	0	0	22
Delays in treatment	Errors in the logistics for transporting patients	0	0	0	0	21
Delays in treatment	Ability to access the dentist	0	0	0	0	17
Delays in treatment	Dental laboratory errors	0	0	0	0	17
Delays in treatment	IT - Software errors	0	0	0	0	12
Breaches of confidentiality	0	0	Failure to adhere to procedures or regulations	0	0	11
Record not up to date or information missing	0	0	0	0	0	11
Delays in treatment	Equipment failure	0	Lack of equipment maintenance	0	0	10
Delays in treatment	Errors in managing appointments	0	Insufficient staff members	0	0	10
Incorrect or unavailable documentation	IT - Software errors	0	0	0	0	10
Inefficient transfer of information between healthcare settings	0	0	0	0	0	10
Delays in treatment	0	0	0	0	0	9
Errors in the logistics for transporting patients	0	0	0	0	0	8
Delays in treatment	Insufficient supplies	0	0	0	0	7
Dental laboratory errors	0	0	0	0	0	7

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Inappropriate professional conduct from healthcare professional	0	0	0	0	0	7
Delays in treatment	0	0	Lack of supplies	0	0	6
Insufficient supplies	0	0	0	0	0	6
Communication errors between dentist and patient	0	0	0	0	0	5
Delays in treatment	Equipment failure	0	0	0	0	5
Delays in treatment	Errors in managing appointments	Communication errors between professionals	0	0	0	5
Delays in treatment	Ability to access the dentist	Errors in the logistics for transporting patients	0	0	0	5
Delays in treatment	Incorrect or unavailable documentation	0	0	0	0	5
Delays in treatment	Incorrect or unavailable documentation	IT - Software errors	0	0	0	5
Ability to access the dentist	0	0	0	0	0	4
Breaches of confidentiality	0	0	0	0	0	4
Delayed referral	0	0	0	0	0	4
Delays in treatment	0	0	Interpreter services unavailable	0	0	4
Errors in managing appointments	0	0	0	0	0	4
Incomplete referral	0	0	0	0	0	4
Wrong medical record	0	0	0	0	0	4
Ability to access the dentist	0	0	Insufficient staff members	0	0	3
Breaches of confidentiality	0	0	Distraction	0	0	3
Communication errors between professionals	0	0	0	0	0	3
Delays in treatment	0	0	Busy or overloaded dental practice	0	0	3
Delays in treatment	Insufficient supplies	0	Lack of supplies	0	0	3

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Delays in treatment	Interpreter services not available or non-attendance	0	0	0	0	3
Delays in treatment	Interpreter services not available or non-attendance	0	Patient unable to communicate in English	0	0	3
Delays in treatment	Communication errors between staff and patients	0	0	0	0	3
Errors in managing appointments	0	0	Busy or overloaded dental practice	0	0	3
Errors in the logistics for transporting patients	Communication errors between professionals	0	0	0	0	3
Errors in the logistics for transporting patients	Errors in managing appointments	Communication errors between professionals	0	0	0	3
Inaccurate information on record	0	0	0	0	0	3
Insufficient assessment in history /examination	0	0	0	0	0	3
Insufficient supplies	0	0	Lack of supplies	0	0	3
Ability to access the dentist	Equipment failure	0	0	0	0	2
Delays in treatment	0	0	Lack of equipment maintenance	0	0	2
Delays in treatment	Errors in the professional conduct of healthcare professionals	0	Busy or overloaded dental practice	0	0	2
Delays in treatment	IT - Software errors	0	Lack of equipment maintenance	0	0	2
Delays in treatment	Errors in managing appointments	0	Failure to provide continuity of care between healthcare professionals	0	0	2
Delays in treatment	Errors in the logistics for transporting patients	Errors in managing appointments	0	0	0	2
Delays in treatment	Communication errors between professionals	0	0	0	0	2
Delays in treatment	Interpreter services not available or non-attendance	Errors in managing appointments	Patient unable to communicate in English	0	0	2
Errors in choosing the correct process or procedure	0	0	Distraction	0	0	2

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Errors in managing appointments	Incorrect or unavailable documentation	0	0	0	0	2
Inaccurate laboratory test results	0	0	0	0	0	2
Inefficient transfer of information between healthcare settings	0	0	Distraction	0	0	2
Insufficient supplies	Failure to comply with infection control standard procedures	0	0	0	0	2
Ability to access the dentist	Equipment failure	0	Lack of equipment maintenance	0	0	1
Breaches of confidentiality	Errors in managing appointments	0	0	0	0	1
Breaches of confidentiality	Errors in the professional conduct of healthcare professionals	0	0	0	0	1
Breaches of confidentiality	Errors in the taking and distribution of messages	0	0	0	0	1
Breaches of confidentiality	Inaccurate information on record	Communication errors between staff and patient	Failure to adhere to procedures or regulations	0	0	1
Breaches of confidentiality	Incorrect or unavailable documentation	0	Failure to adhere to procedures or regulations	0	0	1
Breaches of confidentiality	Inefficient transfer of information between healthcare settings	0	Distraction	0	0	1
Breaches of confidentiality	Insufficient supplies	0	Lack of supplies	0	0	1
Breaches of confidentiality	IT - Software errors	0	IT - Technical failure	0	0	1
Breaches of confidentiality	Wrong medical record	0	Distraction	0	0	1
Breaches of confidentiality	Wrong medical record	0	Failure to adhere to procedures or regulations	0	0	1
Communication errors between dentist and patient	0	0	Patient's previous health related conditions	0	0	1
Communication errors between professionals	0	0	Failure to provide continuity of care between healthcare professionals	0	0	1

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Communication errors between professionals	Wrong medical record	0	Thinking error - mistake - action as planned but decision was wrong	Patient unable to communicate in English	0	1
Communication errors between staff and patients	Wrong medical record	0	Thinking error - mistake - action as planned but decision was wrong	0	0	1
Communication errors between staff and patients	0	0	Non-compliance from the patient	0	0	1
Communication errors between staff and patients	0	0	0	0	0	1
Delayed assessment	Equipment failure	0	Lack of equipment maintenance	0	0	1
Delayed diagnosis	0	0	0	0	0	1
Delayed referral	Inefficient transfer of information between healthcare settings	0	0	0	0	1
Delays in treatment	0	0	Dental laboratory errors	0	0	1
Delays in treatment	0	0	Distraction	0	0	1
Delays in treatment	0	0	Failure to adhere to procedures or regulations	0	0	1
Delays in treatment	Inefficient transfer of information between healthcare settings	0	0	0	0	1
Delays in treatment	0	0	Non-compliance from the patient	0	0	1
Delays in treatment	Insufficient assessment in history /examination	Communication errors between professionals	Failure to provide continuity of care between healthcare professionals	0	0	1
Delays in treatment	Equipment failure	IT - Software errors	0	0	0	1
Delays in treatment	Insufficient supplies	0	Inadequate or unavailable policies or guidelines to follow	0	0	1
Delays in treatment	0	0	Patient's previous health related conditions	0	0	1
Delays in treatment	Errors in managing appointments	Communication errors between dentist and patient	0	0	0	1

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Delays in treatment	Dental laboratory errors	Errors in the taking and distribution of messages	0	0	0	1
Delays in treatment	Ability to access the dentist	Communication errors between professionals	0	0	0	1
Delays in treatment	Ability to access the dentist	0	Distraction	0	0	1
Delays in treatment	0	0	Busy or overloaded dental practice	Insufficient staff members	0	1
Delays in treatment	Failure to comply with infection control standard procedures	0	0	0	0	1
Delays in treatment	Errors in managing appointments	Communication errors between staff and patient	0	0	0	1
Delays in treatment	Errors in managing appointments	Errors in the logistics for transporting patients	0	0	0	1
Delays in treatment	Ability to access the dentist	Equipment failure	Lack of equipment maintenance	0	0	1
Delays in treatment	Errors in managing appointments	IT - Software errors	0	0	0	1
Delays in treatment	Incorrect or unavailable documentation	Inefficient transfer of information between healthcare settings	0	0	0	1
Delays in treatment	Errors in managing appointments	IT - Technical errors	0	0	0	1
Delays in treatment	Errors in managing appointments	0	Busy or overloaded dental practice	Insufficient staff members	0	1
Delays in treatment	Errors in the logistics for transporting patients	Communication errors between dentist and patient	0	0	0	1
Delays in treatment	0	0	Interpreter services unavailable	Insufficient staff members	0	1
Delays in treatment	Incorrect or unavailable documentation	0	Failure to adhere to procedures or regulations	0	0	1
Delays in treatment	Errors in the logistics for transporting patients	Communication errors between professionals	0	0	0	1
Delays in treatment	Communication errors between dentist and patient	0	Non-compliance from the patient	0	0	1

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Delays in treatment	Errors in managing appointments	Communication errors between professionals	Lack of supplies	Patient's previous health related conditions	Thinking error - mistake - action as planned but decision was wrong	1
Delays in treatment	Errors in managing appointments	0	Patient unable to communicate in English	0	0	1
Delays in treatment	Incomplete referral	0	0	0	0	1
Delays in treatment	Failure to comply with infection control standard procedures	0	Inadequate or unavailable policies or guidelines to follow	0	0	1
Delays in treatment	Incorrect or unavailable documentation	0	Insufficient staff members	0	0	1
Delays in treatment	Communication errors between professionals	0	Distraction	0	0	1
Delays in treatment	Information filled incorrectly	0	0	0	0	1
Delays in treatment	Record not up to date or information missing	0	0	0	0	1
Delays in treatment	Errors in choosing the correct process or procedure	Errors in managing appointments	Insufficient staff members	0	0	1
Dental laboratory errors	Incorrect or unavailable documentation	0	0	0	0	1
Dental laboratory errors	0	0	Inadequate skills / knowledge	0	0	1
Errors in choosing the correct process or procedure	0	0	0	0	0	1
Errors in choosing the correct process or procedure	0	0	Pregnant patient	0	0	1
Errors in choosing the correct process or procedure	Errors in obtaining the informed consent	0	0	0	0	1
Errors in choosing the correct process or procedure	Errors in the professional conduct of healthcare professionals	0	0	0	0	1
Errors in choosing the correct process or procedure	Inefficient transfer of information between healthcare settings	0	0	0	0	1
Errors in choosing the correct process or procedure	Insufficient assessment in history /examination	0	Non-compliance from the patient	0	0	1
Errors in managing appointments	Communication errors between professionals	0	0	0	0	1

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Errors in managing appointments	Inefficient transfer of information between healthcare settings	0	0	0	0	1
Errors in managing appointments	IT - Software errors	0	0	0	0	1
Errors in managing appointments	IT - Technical errors	0	0	0	0	1
Errors in managing appointments	0	0	Distraction	0	0	1
Errors in managing appointments	0	0	Insufficient staff members	0	0	1
Errors in managing appointments	Communication errors between professionals	0	Interpreter services unavailable	0	0	1
Errors in managing appointments	0	0	Lack of equipment maintenance	0	0	1
Errors in managing appointments	IT - Software errors	0	Lack of equipment maintenance	0	0	1
Errors in managing appointments	Incorrect or unavailable documentation	Equipment failure	Thinking error - mistake - action as planned but decision was wrong	Lack of equipment maintenance	0	1
Errors in obtaining the informed consent	0	0	Interpreter services unavailable	0	0	1
Errors in obtaining the informed consent	0	0	0	0	0	1
Errors in obtaining the informed consent	0	0	Distraction	Interpreter services unavailable	0	1
Errors in the logistics for transporting patients	0	0	Insufficient staff members	0	0	1
Errors in the logistics for transporting patients	Equipment failure	0	Lack of equipment maintenance	0	0	1
Errors in the process of payment systems	0	0	0	0	0	1
Errors in the process of payment systems	IT - Software errors	0	0	0	0	1
Failure to follow-up	0	0	0	0	0	1
Inaccurate information on record	Errors in obtaining or processing x-rays	0	0	0	0	1

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Inaccurate information on record	Inefficient transfer of information between healthcare settings	0	0	0	0	1
Inaccurate information on record	Inefficient transfer of information between healthcare settings	IT - Software errors	0	0	0	1
Inaccurate information on record	Insufficient assessment in history /examination	0	0	0	0	1
Inaccurate information on record	IT - Software errors	0	0	0	0	1
Inaccurate information on record	0	0	Distraction	0	0	1
Inaccurate information on record	0	0	Thinking error - mistake - action as planned but decision was wrong	0	0	1
Inappropriate professional conduct from healthcare professional	Errors in obtaining the informed consent	0	0	0	0	1
Incomplete referral	Communication errors between dentist and patient	0	0	0	0	1
Incomplete referral	Inefficient transfer of information between healthcare settings	0	0	0	0	1
Incomplete referral	Record not up to date or information missing	0	0	0	0	1
Incomplete referral	0	0	Distraction	0	0	1
Incorrect or unavailable documentation	Errors in obtaining or processing x-rays	IT - Software errors	0	0	0	1
Incorrect or unavailable documentation	Inefficient transfer of information between healthcare settings	0	0	0	0	1
Incorrect or unavailable documentation	IT - Technical errors	0	0	0	0	1
Incorrect or unavailable documentation	IT - User errors	0	0	0	0	1
Incorrect or unavailable documentation	Record not up to date or information missing	0	0	0	0	1

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Incorrect or unavailable documentation	0	0	Busy or overloaded dental practice	0	0	1
Incorrect or unavailable documentation	0	0	Distraction	0	0	1
Incorrect or unavailable documentation	IT - Software errors	0	Lack of equipment maintenance	0	0	1
Incorrect or unavailable documentation	0	0	Thinking error - mistake - action as planned but decision was wrong	0	0	1
Inefficient transfer of information between healthcare settings	Equipment failure	0	0	0	0	1
Inefficient transfer of information between healthcare settings	0	0	Failure to provide continuity of care between healthcare professionals	0	0	1
Inefficient transfer of information between healthcare settings	0	0	Inadequate or unavailable policies or guidelines to follow	0	0	1
Information filled incorrectly	Inappropriate professional conduct from healthcare professional	0	0	0	0	1
Information filled incorrectly	0	0	0	0	0	1
Insufficient assessment in history /examination	Errors in obtaining the informed consent	0	0	0	0	1
Insufficient assessment in history /examination	Errors in obtaining the informed consent	0	Failure to adhere to procedures or regulations	Inadequate leadership	0	1
Insufficient assessment in history /examination	0	0	Lack of supplies	0	0	1
Insufficient supplies	0	0	Lack of equipment maintenance	0	0	1
Insufficient supplies	Communication errors between professionals	0	Lack of supplies	0	0	1
Interpreter services not available or non-attendance	0	0	Interpreter services unavailable	0	0	1
Interpreter services not available or non-attendance	0	0	0	0	0	1
Missed diagnosis	0	0	0	0	0	1

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Record not up to date or information missing	IT - Software errors	0	0	0	0	1
Record not up to date or information missing	0	0	Failure to adhere to procedures or regulations	0	0	1
Record not up to date or information missing	Communication errors between professionals	0	Insufficient staff members	0	0	1
Record not up to date or information missing	0	0	Patient's previous history on allergies	0	0	1
Unnecessary referral	Insufficient supplies	0	Lack of supplies	0	0	1
Wrong medical record	Errors in managing appointments	0	0	0	0	1

Appendix 13. Distribution of combinations in the intra-operative stage

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Medication-related adverse incidents	0	0	0	0	0	117
Procedural error	0	0	0	0	0	65
Procedural error	0	0	Distraction	0	0	65
Broken instrument	0	0	0	0	0	56
Equipment failure	0	0	0	0	0	41
Equipment failure	0	0	Lack of equipment maintenance	0	0	39
Other procedural complications	0	0	0	0	0	24
Procedural error	0	0	Unexpected movement of the patient	0	0	23
Ingestion / inhalation of foreign body	0	0	0	0	0	21
Medication-related adverse incidents	0	0	Patient's previous health related conditions	0	0	20
Procedural error	0	0	Inadequate skills / knowledge	0	0	20
Wrong tooth extracted	0	0	Distraction	0	0	19
Errors in obtaining or processing x-rays	0	0	0	0	0	18
Errors in obtaining or processing x-rays	0	0	Distraction	0	0	18
Procedural error	Equipment failure	0	0	0	0	17
Errors in obtaining or processing x-rays	IT - Software errors	0	0	0	0	11
Wrong tooth extracted	0	0	0	0	0	10
Failure to comply with infection control standard procedures	0	0	Failure to adhere to procedures or regulations	0	0	9
Broken instrument	Procedural error	0	0	0	0	8

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Failure to comply with infection control standard procedures	0	0	0	0	0	8
Medication-related adverse incidents	0	0	Non-compliance from the patient	0	0	7
Procedure performed on wrong anatomical side or site	0	0	Distraction	0	0	7
Equipment failure	0	0	Poor equipment design	0	0	6
Errors in obtaining or processing x-rays	Equipment failure	0	0	0	0	6
Failure to comply with infection control standard procedures	0	0	Inadequate or unavailable policies or guidelines to follow	0	0	6
Errors in obtaining or processing x-rays	0	0	Inadequate skills / knowledge	0	0	5
Insufficient supplies	0	0	Lack of supplies	0	0	5
Wrong tooth extracted	Inefficient transfer of information between healthcare settings	0	0	0	0	5
Medication-related adverse incidents	0	0	Patient's previous history on allergies	0	0	4
Procedural error	0	0	Gag reflex	0	0	4
Ingestion / inhalation of foreign body	Equipment failure	0	0	0	0	4
Ingestion / inhalation of foreign body	0	0	Distraction	0	0	4
Broken instrument	0	0	Lack of equipment maintenance	0	0	3
Broken instrument	0	0	Poor equipment design	0	0	3
Broken instrument	0	0	Unexpected movement of the patient	0	0	3
Errors in obtaining or processing x-rays	Communication errors between professionals	0	0	0	0	3
Errors in obtaining or processing x-rays	Equipment failure	0	0	0	0	3
Errors in obtaining or processing x-rays	Equipment failure	IT - Software errors	0	0	0	3

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Ingestion / inhalation of foreign body	Broken instrument	0	0	0	0	3
Ingestion / inhalation of foreign body	0	0	Gag reflex	0	0	3
Insufficient supplies	0	0	0	0	0	3
Broken instrument	0	0	Inadequate skills / knowledge	0	0	2
Broken instrument	Procedural error	0	Inadequate skills / knowledge	0	0	2
Procedural error	Insufficient assessment in history /examination	0	0	0	0	2
Procedural error	Insufficient supplies	0	0	0	0	2
Procedural error	0	0	Non-compliance from the patient	0	0	2
Procedural error	Insufficient assessment in history /examination	0	Patient's previous history on allergies	0	0	2
Procedural error	Equipment failure	0	Poor equipment design	0	0	2
Errors in obtaining or processing x-rays	Equipment failure	0	0	0	0	2
Errors in obtaining or processing x-rays	Equipment failure	IT - Software errors	0	0	0	2
Errors in obtaining or processing x-rays	0	0	Failure to adhere to procedures or regulations	0	0	2
Errors in obtaining or processing x-rays	Equipment failure	0	Lack of equipment maintenance	0	0	2
Errors in obtaining or processing x-rays	0	0	Unexpected movement of the patient	0	0	2
Errors in the process of administering a medication	0	0	Distraction	0	0	2
Errors in the process of administering a medication	Supplies out of date	0	0	0	0	2
Insufficient supplies	0	0	0	0	0	2
Broken instrument	Equipment failure	0	0	0	0	1
Broken instrument	Procedural error	0	Distraction	0	0	1
Broken instrument	Procedural error	0	Distraction	Lack of equipment maintenance	0	1

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Broken instrument	Equipment failure	0	Lack of equipment maintenance	0	0	1
Broken instrument	Equipment failure	0	Poor equipment design	0	0	1
Broken instrument	Procedural errors	0	Poor equipment design	0	0	1
Medication-related adverse incidents	Accidental injection of dental material into soft tissues	Procedural error	0	0	0	1
Medication-related adverse incidents	Procedural error	0	0	0	0	1
Medication-related adverse incidents	Procedural error	0	0	0	0	1
Medication-related adverse incidents	0	0	Distraction	0	0	1
Medication-related adverse incidents	Inappropriate professional conduct from healthcare professional	0	Non- compliance from the patient	0	0	1
Medication-related adverse incidents	Insufficient assessment in history /examination	0	Patient unable to communicate in English	0	0	1
Medication-related adverse incidents	0	0	Non-compliance from the patient	Patient's previous health related conditions	0	1
Medication-related adverse incidents	0	0	Patient's pregnancy	0	0	1
Medication-related adverse incidents	Incorrect or unavailable documentation	IT - Software errors	Patient's previous health related conditions	0	0	1
Medication-related adverse incidents	Record not up to date or information missing	0	Patient's previous history on allergies	0	0	1
Medication-related adverse incidents	0	0	Patient's previous health related conditions	Failure to adhere to procedures or regulations	0	1
Medication-related adverse incidents	0	0	Patient's previous history on allergies	Distraction	0	1
Complication as a result of the dental material used	0	0	0	0	0	1
Contraindicated dental material used	Insufficient assessment in history /examination	0	Distraction	Pregnant patient	0	1
Equipment failure	Insufficient supplies	0	0	0	0	1
Equipment failure	IT - Software errors	0	0	0	0	1

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Equipment failure	0	0	Inadequate skills / knowledge	0	0	1
Equipment failure	IT - Software errors	0	Lack of equipment maintenance	0	0	1
Equipment not available	0	0	0	0	0	1
Errors in choosing the correct process or procedure	0	0	Failure to adhere to procedures or regulations	Insufficient staff members	0	1
Procedural error	Communication errors between professionals	Communication errors between professionals	0	0	0	1
Procedural error	Communication errors between professionals	0	0	0	0	1
Procedural error	Out of date medication	0	0	0	0	1
Procedural error	Supplies out of date	0	0	0	0	1
Procedural error	0	0	Distraction	Inadequate skills / knowledge	0	1
Procedural error	Wrong medical record	0	Distraction	0	0	1
Procedural error	Wrong medical record	0	Distraction	Thinking error - mistake - action as planned but decision was wrong	0	1
Procedural error	0	0	Equipment failure	0	0	1
Procedural error	Insufficient supplies	0	Equipment failure	0	0	1
Procedural error	0	0	Failure to adhere to procedures or regulations	0	0	1
Procedural error	Insufficient assessment in history /examination	0	Failure to adhere to procedures or regulations	0	0	1
Procedural error	Incorrect or unavailable documentation	0	Inadequate or unavailable policies or guidelines to follow	0	0	1
Procedural error	0	0	Insufficient staff members	0	0	1
Procedural error	Equipment failure	0	Lack of equipment maintenance	0	0	1
Procedural error	Communication errors between dentist and patient	0	Non-compliance from the patient	0	0	1
Procedural error	0	0	Patient's previous history on allergies	0	0	1

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Errors in obtaining a biopsy	0	0	Failure to adhere to procedures or regulations	0	0	1
Errors in obtaining a biopsy	0	0	Insufficient staff members	0	0	1
Errors in obtaining or processing x-rays	Equipment failure	IT - Software errors	0	0	0	1
Errors in obtaining or processing x-rays	Equipment failure	0	0	Lack of equipment maintenance	0	1
Errors in obtaining or processing x-rays	Incorrect or unavailable documentation	0	0	0	0	1
Errors in obtaining or processing x-rays	Inefficient transfer of information between healthcare settings	0	0	0	0	1
Errors in obtaining or processing x-rays	Lost equipment	0	0	0	0	1
Errors in obtaining or processing x-rays	Equipment failure	0	Distraction	0	0	1
Errors in obtaining or processing x-rays	Errors in managing appointments	0	Distraction	0	0	1
Errors in obtaining or processing x-rays	Insufficient supplies	0	Distraction	0	0	1
Errors in obtaining or processing x-rays	Incorrect or unavailable documentation	0	Failure to provide continuity of care between healthcare professionals	0	0	1
Errors in obtaining or processing x-rays	Communication errors between professionals	0	Inadequate skills / knowledge	0	0	1
Errors in the process of administering a medication	Supplies out of date	0	Distraction	0	0	1
Errors in the process of administering a medication	Communication errors between professionals	0	Insufficient staff members	0	0	1
Errors in the process of administering a medication	Incorrect or unavailable documentation	IT - Software errors	0	0	0	1
Errors in the process of administering a medication	Supplies out of date	0	Failure to adhere to procedures or regulations	Distraction	0	1
Failure to comply with infection control standard procedures	Equipment failure	0	0	0	0	1
Failure to comply with infection control standard procedures	0	0	Distraction	0	0	1

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Failure to comply with infection control standard procedures	Communication errors between professionals	0	Distraction	0	0	1
Failure to comply with infection control standard procedures	Communication errors between professionals	0	Inadequate or unavailable policies or guidelines to follow	Distraction	0	1
Failure to comply with infection control standard procedures	Errors in the professional conduct of healthcare professionals	0	Inadequate or unavailable policies or guidelines to follow	0	0	1
Failure to comply with infection control standard procedures	0	0	Insufficient staff members	0	0	1
Failure to comply with infection control standard procedures	Equipment failure	0	Lack of equipment maintenance	0	0	1
Ingestion / inhalation of foreign body	Procedural error	0	0	0	0	1
Ingestion / inhalation of foreign body	Equipment failure	0	Distraction	0	0	1
Ingestion / inhalation of foreign body	Procedural error	0	Gag reflex	Inadequate skills / knowledge	0	1
Ingestion / inhalation of foreign body	0	0	Inadequate skills / knowledge	0	0	1
Ingestion / inhalation of foreign body	0	0	Poor equipment design	0	0	1
Ingestion / inhalation of foreign body	Procedural error	0	Poor equipment design	0	0	1
Ingestion / inhalation of foreign body	0	0	Unexpected movement of the patient	0	0	1
Insufficient supplies	0	0	Inadequate skills / knowledge	0	0	1
Lost equipment	Communication errors between professionals	0	0	0	0	1
Other procedural complications	0	0	Patient's previous health related conditions	0	0	1
Other procedural complications	0	0	Patient's previous history on allergies	0	0	1
Procedure performed on wrong anatomical side or site	0	0	0	0	0	1
Procedure performed on wrong anatomical side or site	Communication errors between professionals	0	Distraction	0	0	1

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Procedure performed on wrong anatomical side or site	Errors in obtaining or processing x-rays	0	Distraction	0	0	1
Procedure performed on wrong anatomical side or site	Incorrect or unavailable documentation	0	0	0	0	1
Supplies out of date	0	0	0	0	0	1
Unexpected movement from staff	0	0	Distraction	0	0	1
Wrong instrument used	Communication errors between professionals	0	Distraction	0	0	1
Wrong tooth extracted	0	0	Inadequate skills / knowledge	0	0	1
Wrong tooth extracted	0	0	Thinking error - mistake - action as planned but decision was wrong	0	0	1
Wrong tooth extracted	Errors in obtaining the informed consent	0	0	0	0	1
Wrong tooth extracted	Insufficient assessment in history /examination	0	0	0	0	1
Wrong tooth extracted	Insufficient assessment in history /examination	0	Distraction	0	0	1

Appendix 14. Distribution of combinations in the post-operative stage

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Errors in the process of delivering a medication	0	0	0	0	0	6
Contraindicated medication prescribed / dispensed	0	0	Patient's previous history on allergies	0	0	5
Unintentional drug overdose (self-administered)	0	0	0	0	0	4
Wrong dose prescribed	0	0	0	0	0	4
Medication incorrectly stored	0	0	0	0	0	3
Wrong medication / treatment given	0	0	Distraction	0	0	3
Contraindicated medication prescribed / dispensed	0	0	Distraction	Patient's previous history on allergies	0	2
Contraindicated medication prescribed / dispensed	Insufficient assessment in history /examination	0	0	0	0	2
Contraindicated medication prescribed / dispensed	0	0	0	0	0	1
Contraindicated medication prescribed / dispensed	Errors in choosing the correct process or procedure	0	Distraction	0	0	1
Contraindicated medication prescribed / dispensed	Insufficient assessment in history /examination	0	Patient's previous history on allergies	0	0	1
Contraindicated medication prescribed / dispensed	0	0	Patient's previous history on allergies	Inadequate skills / knowledge	0	1
Contraindicated medication prescribed / dispensed	0	0	Pregnant patient	Inadequate skills / knowledge	0	1
Contraindicated medication prescribed / dispensed	Incorrect or unavailable documentation	0	Non-compliance from the patient	Patient or parent has poor understanding	0	1
Errors in the process of delivering a medication	Communication errors between dentist and patient	0	0	0	0	1
Errors in the process of delivering a medication	Inefficient transfer of information between healthcare settings	0	0	0	0	1
Errors in the process of delivering a medication	0	0	Distraction	0	0	1

Primary incident	Contributory incident 1	Contributory incident 2	Contributory factor 1	Contributory factor 2	Contributory factor 3	Frequency
Errors in the process of delivering a medication	0	0	Non-compliance from the patient	0	0	1
Lost prescription	0	0	0	0	0	1
Lost prescription	Lost prescription	0	0	0	0	1
Medication incorrectly stored	0	0	Inadequate or unavailable policies or guidelines to follow	0	0	1
Medication incorrectly stored	Supplies out of date	0	0	0	0	1
Medication not available	0	0	0	0	0	1
Medication not available	Supplies out of date	0	0	0	0	1
Medication not available	Communication errors between professionals	0	0	0	0	1
No medication/treatment given when appropriate	Communication errors between dentist and patient	0	Non-compliance from the patient	0	0	1
Wrong dose prescribed	Communication errors between professionals	0	0	0	0	1
Wrong dose prescribed	0	0	Distraction	0	0	1
Wrong dose prescribed	Inefficient transfer of information between healthcare settings	0	Inadequate skills / knowledge	0	0	1
Wrong medication / treatment given	0	0	0	0	0	1
Wrong medication prescribed	0	0	Patient's previous history on allergies	0	0	1

Appendix 15. Ethical approval for the first round

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15 August 2016

Eduardo Ensaldo Carrasco

Dear Eduardo

Re: Evidence-based priority setting for patient safety research on never events in ambulatory dental care: Delphi study

Thank you for resubmitting your documentation addressing the final two conditions that were imposed by the CPHS ethics committee. Your response and the completion of the information sheet have been judged satisfactory. I am therefore pleased to be able to inform you that the above study has been granted ethical approval *up to an including only the first questionnaire*.

Please be aware that this ethical approval is in respect of the protocol and methods as described in the documents submitted to the committee (with amended documents superseding predecessors). Therefore, as noted above, in due course *you will need to submit the second and third questionnaires as amendments*, for approval, prior to circulating them to study participants.

In addition, if there is in the future *any other change* needed to the study design/protocol/methods, you should check whether this means your level 2 application form needs to be revised, and submit to the committee (via me), any documents that have been revised (study materials/protocol/level 2 form), using tracked changes. You should make clear in your covering email whether:

(i) The amendment you are submitting for approval is the 2nd/3rd questionnaire, as anticipated; and/or

(ii) You wish to make some other amendment to study design/methods and –

a. you are requesting ethical review of this; or

b. you are not sure whether ethical review is needed and, in the first instance, would like the committee's opinion on whether the amendment requires formal approval.

Yours sincerely

Diane White

Diane White
Ethics Review Group Administrator

Usher Institute
Population Health Sciences & Informatics

CPHS: http://www.cphs.mvm.ed.ac.uk
Ethical Review Group : http://www.cphs.mvm.ed.ac.uk/intra/research/ethicalReview.php (Staff & PGR Students only)

Appendix 16. Ethical approval for the second round

THE UNIVERSITY *of* EDINBURGH

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01 December 2016

Eduardo Ensaldo Carrasco

Dear Eduardo

Re: Evidence-based priority setting for patient safety research on never events in ambulatory dental care: Delphi study – Amendment Questionnaire 2

Thank you for submitting a revised version of Questionnaire 2. This questionnaire has now been judged satisfactory. I am therefore pleased to be able to inform you that this questionnaire, for the next stage of your research, is acceptable. Therefore your (amended) research has been granted ethical approval *up to and including the second stage questionnaire*.

Please be aware that this ethical approval is in respect of the protocol and methods as described in the documents submitted to the committee (with amended documents superseding predecessors). Therefore, as noted above, in due course *you will need to submit the third questionnaires as an amendment*, for approval, prior to circulating it to study participants.

The edits suggested for Questionnaire 2, by the Ethics Committee, comprised a *considerable workload*, whereas providing such details individual study is *not* part of their remit. This was done in this case in the interests of saving you time, because it was judged that otherwise a number of iterations would be needed. Please make sure when you submit Questionnaire 3 for approval, that you have applied to its design, wording and formatting, the same principles as underpin the 'suggestions' the Ethics Committee made about the Qu 2. It is highly unlikely that for Qu 3 such an 'suggested edit' will be forthcoming from the committee.

Please also remember that if there is in the future *any other change* needed to the study design/protocol/methods, you should check whether this means your level 2 application form needs to be revised, and submit to the committee (via me), any documents that have been revised (study materials/protocol/level 2 form), using tracked changes. You should make clear in your covering email whether:

(i) The amendment you are submitting for approval is the 3rd questionnaire, as anticipated; and/or

(ii) You wish to make some other amendment to study design/methods and –
   a. you are requesting ethical review of this; or
   b. you are not sure whether ethical review is needed and, in the first instance, would like the committee's opinion on whether the amendment requires formal approval.

Yours sincerely

Diane White

Diane White
Ethics Review Group Administrator

Appendix 17. Sample e-mail invitation

"Evidence-based priority setting for patient safety research on never events in primary dental care: Delphi study"

Dear (expert's name),

We would like to invite you to participate, as an expert in the field, in a Delphi study to refine an expert consensus-based list of 'never events' in primary dentistry we have previously developed. These events are defined as serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented.[19] However, despite the ongoing progress being made in medicine, the evidence in relation to dental never events is far less developed.

Given your expertise, you are in the ideal position to provide us valuable first hand feedback for generating this list. The study comprises a series of up to three questionnaires. Each questionnaire takes around 15 minutes to complete. Please be assured that your responses will be treated in the strictest confidence.

Your participation will be a valuable addition to patient safety research in primary care dentistry. The findings of this study will help to inform further research initiatives concerning patient safety in primary care dentistry. The findings also have the potential to inform the development of future policies for the prevention of never events in dentistry at a national and international level. You will be provided with feedback of the study results should you wish to receive it.

If you are willing to participate, please let us know and we will send you further information.

Thank you for considering this request,

Eduardo Ensaldo Carrasco

Appendix 18. Information sheet for Delphi study

Evidence-based priority setting for patient safety research on never events in primary dental care: an international Delphi study

You are being invited to participate in the above study. Before deciding whether to participate or not, we wish to inform you why we are undertaking this study, our approach and what we are asking you to do. This Information Sheet also indicates how we will collect, store and use the data collected. We appreciate you are busy and would like to thank you in advance for taking the time to read this Information Sheet and considering this request.

Background

Unintended harm in patients as a result of the care they receive has been a concern in medicine for the past 20 years. Nowadays, the accumulated evidence in this field has moved from the identification and understanding of these to the implementation of strategies to reduce harm. 'Never events' are an area that has received attention due to their high potential to cause severe harm. These events are defined as serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented (e.g. wrong tooth extraction). However, despite the ongoing progress being made in medicine, the evidence in relation to dental never events is far less developed. Only wrong-tooth extractions has been reported under the domain of "wrong site surgery" as never events in dental practices within the National Health Service in the United Kingdom.

The Delphi technique is a formal structural process for generating consensus among a group of experts based on feedback obtained from their anonymous responses. This methodological approach is favoured in cases where little to no empirical or historical data exist (e.g. never events in dentistry). We believe your expert-feedback will help us to fill this gap and seek to, with your help, refine an expert consensus-based list of 'never events' in primary care dentistry we have previously developed.

Purpose of the study

The purpose of this study is to generate an expert consensus-based list of 'never events' in primary care dentistry.

Why have I been chosen?

You have been identified as an expert in patient safety in dentistry because you have:

- More than three years of active clinical experience;
- More than three years of active academic experience;
- Any experience in leadership roles within national dental associations.
- Any experience in patient safety at a clinical or organisational level

As an established expert in your field, we are looking for your opinion about possible never events in primary care dentistry. Specifically, we would like to ask to you to rank never events

from an initial list we have developed. In addition, we would like to know your opinions on further possible additions to the list provided.

We would like to invite you to participate, as an expert in the field, in a Delphi study to refine an expert consensus-based list of 'never events' in primary care dentistry we have previously developed.

Please read this information sheet carefully.

Do I have to take part?
No. It is entirely up to you if you wish to participate. If you agree, you will still be free to withdraw at any time and without giving a reason. If you do decide to take part you will need to complete the Consent Form and should also keep this Information Sheet.

What will happen if I decide to take part?
As a Delphi panel member, you will be invited to complete a brief questionnaire in order to rank a list of potential never events using an online survey. The estimated time for answering the questionnaire is about 15 minutes. Since the purpose of the study is to build consensus, for the following rounds you will receive an anonymised summary of the responses of the whole group. It usually takes up to three rounds to build consensus. In order to allow timely conclusion of the study we would respectfully request a response time of two weeks for completion of each round. This will allow us to complete the entire process in a timely fashion. Your overall time commitment is expected to be less than 1 hour in total.

What are the possible disadvantages or risks of taking part?
Taking part in the surveys will take up some of your time. There are no risks involved in participating.

What are the possible benefits of taking part?
Your participation in this study will help us to identify events that should never happen in primary care dentistry. The generated list, based on your expertise and experience, will be used to identify research priorities that can be used in evaluative studies and in due course help to develop interventions and guidelines for prevention strategies to improve the safety of primary care dentistry.

Will my participation in the study remain confidential?
Yes. All responses will be strictly confidential and your identity will not be divulged to other participants. Once we collect the answered survey, we will remove your identification details and assign a number to each questionnaire. Then, we will only extract your responses and comments into a customised Excel sheet for further analysis.

Free-text answers may be used as part of the study to assess and modify the list of never events for each round. However, these will not be attributed to you.

Survey responses will be collected online and stored within a password-protected desktop computer at the Centre for Population Health Sciences at the University of Edinburgh, Scotland.

Which tasks will I be expected to do?

The Delphi study requires your participation in up to three consecutive and structured questionnaires. The first constitutes a list of candidate never event identified from the literature and analysis from patient safety incident reports submitted to the National Reporting Learning System. Initially, you will be asked to read this list and assign predefined scores in a structured questionnaire. If you feel necessary, you can comment on how this list can be improved either by modifying, adding or removing items. Then, the responses will be collected and the findings will be analysed and summarised for you to see and these will form the basis of the second questionnaire and third questionnaire if necessary. You will be asked again to assign predefined scores and to provide feedback for the second questionnaire and, if needed, for the third. The decision to conduct a third round will depend on the level of consensus reached at the end of the second round. If this is greater or equal to 80% we will interpret it as a satisfactory agreement and will consider the study completed.

What will happen to the results of this study?

The results of this study will help to inform further research initiatives concerning patient safety in ambulatory dentistry. The findings also have the potential to inform the development of future policies for the prevention of never events in dentistry at a national and international level.

The results of this study will be published in a PhD thesis and relevant academic journals, and presented at conferences. If necessary, the anonymised data may be reused by the research team e.g. if a more in-depth and contextualised approach requires further analysis.

No individual participant will be identifiable in any of the published material.

Who is organizing and funding the research?

This research is part of a larger PhD project hosted by The University of Edinburgh in Scotland and in collaboration with the Primary Care Patient Safety (PISA) Research Group, Cardiff University in Wales.

The Delphi study will be conducted by Eduardo Ensaldo Carrasco, who is being funded by the Mexican National Council for Science and Technology (CONACYT) and Mexico's Ministry of Education (SEP).

Has this study undergone ethical review?

Yes. This study has been granted ethical approval by the Ethics Review Group at the Centre for Population Health Sciences, University of Edinburgh.

What can I do if I have a complaint about the study?

If you have any questions or concerns about this study, please raise them with a member of the research team (all contact details are given below). If you feel that you need to make a formal complaint, please get in touch with Professor David Weller. Centre for Population Health Sciences, University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG. Tel: 0131 650 2807. Fax: (0131) 650 9519; email: David.Weller@ed.ac.uk

Who do I contact for further information?

For further information about this study please contact either:

PhD student: Eduardo Ensaldo Carrasco, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG. email: E.Ensaldo-Carrasco@ed.ac.uk

Kathrin Cresswell, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG. Tel: (0131) 516 7982; email: Kathrin.Beyer@ed.ac.uk

Andrew Carson Stevens, Primary and Emergency Care Research (PRIME) Centre, Cardiff University, Wales; email: andypcs@gmail.com

Raman Bedi. King's College London Dental Institute at Guy's, King's College and St Thomas's Hospitals, Division of Population and Patient Health, King's College London, United Kingdom; email: raman.bedi@kcl.ac.uk

Aziz Sheikh, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG; Tel: 0131 651 4151; email: Aziz.Sheikh@ed.ac.uk

Thank you for taking the time to read this information sheet and for considering this request.

Appendix 19. Delphi study consent form

Evidence-based priority setting for patient safety research on never events in ambulatory dental care: Delphi study

QUESTIONNAIRE CONSENT FORM

Thank you for reading the information sheet about the Delphi study. If you are happy to participate, then please complete and sign the form below. Please initial the box alongside each statement to confirm that each statement is true for you.

	Initials
I have read the information sheet and asked any questions I want, which were answered to my satisfaction (Please note that the information sheet gives the names of people you can contact to discuss the study)	
I have been informed of the objectives of the study, my role within it, and the tasks I am expected to undertake	
I understand that I will be participating in a study to refine an expert consensus-based list of 'never events' in ambulatory dentistry the research team has previously developed	
I understand that I am free to withdraw from the study at any time and without giving a reason for withdrawing	
I have been reassured that my anonymity as a participant will be maintained	
I have been provided with the contact details of the researcher and have details of the complaints procedure that I can use if I wish to	
I agree for the anonymised data to be reused by the research team e.g. if a more in-depth and contextualised approach requires further analysis	
I agree to participate in the study	

Name of participant (capitals): …….

Signed: ……..…… Date: ……..

I would like to receive a summary of the work (expected by November 2016). Please send this to the following email address:_____

Please return to:

Eduardo Ensaldo Carrasco, Usher Institute Population Health Sciences and Informatics, The University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG. email: E.Ensaldo-Carrasco@ed.ac.uk

Appendix 20. First round questionnaire

Appendix 4. Delphi study initial questionnaire

Evidence-based priority setting for patient safety research on never events in ambulatory dental care: Delphi study

Thank you very much for your participation in this Delphi study to refine an expert consensus-based list of 'never events' in ambulatory dentistry we have previously developed. This questionnaire is part of a larger PhD project hosted at The University of Edinburgh in Scotland and in collaboration with the Primary Care Patient Safety (PISA) Research Group at Cardiff University in Wales.

The purpose of this study is to generate an expert consensus-based list of 'never events' in ambulatory dentistry. These events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented.[1] In order to achieve this, you are being provided with a list of candidate never events identified from the literature and analysis from patient safety incident reports submitted to the National Reporting Learning System.

You will be asked to read this list and assign predefined scores in the structured questionnaire provided below.

This questionnaire is the first round out of a maximum of three for the study. Please try to answer all the included items and, if you feel necessary, comment on how this list can be improved either by modifying, adding or removing items.

Once we have retrieved all the responses from participants, the findings will be analysed and summarised for you to see and these will form the basis of the second questionnaire. Participation and individual responses will be kept confidential to the research team.

Thank you.

Reference

1. National Patient Safety Agency. Patient Safety - Never Events: NHS; 2015. Available from: http://www.nrls.npsa.nhs.uk/neverevents/

Instructions: Please assign a number between 1 and 5 for each criteria **(1 being "strongly disagree" and 5 being "strongly agree")** for all the criteria in each candidate never events provided in this questionnaire. These numbers will represent how much you agree for every candidate event to be preventable, serious and to the classified as a never event.

Please remember that never events are defined as serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented.

Please ensure there are no unanswered items.

Candidate never events	Preventable					Serious					Should be classified as a never event					Comments
	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	
Routine assessment																
Missed diagnosis of oral cancer	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Delayed referral of patient with clinical suspicion of cancer	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
[Further never events added from Phase 1 of the research – see protocol]	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Preoperative stage																
Mistaken patient identity	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Failure to prescribe antibiotic prophylaxis before treating root canal infections	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	

Candidate never events	Preventable					Serious					Should be classified as a never event					Comments
	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	
Procedure carried out without the voluntary and signed informed consent	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
[Further never events added from Phase 1 of the research – see protocol]	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Intraoperative stage																
Use of non-sterile instruments or equipment	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Use of dental material in a patient with known history of allergy to the dental material used	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Use of outdated material	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Administration of unlabelled cartridge of local anaesthetics	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Injection of wrong anaesthetic solution	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Treatment performed to a patient with a previously known untreated medical condition that can potentially be exacerbated by the dental treatment	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Ingestion or aspiration of foreign objects	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Wrong tooth treated or extracted	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	

Candidate never events	Preventable					Serious					Should be classified as a never event					Comments
	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	
Sev ere apical tooth resorption due to orthodontic treatment	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Nerv e damage due to errors in treatment plan	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Intrav ascular injection of local anaesthetic	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Acrylic set inside the mouth	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Jaw fracture due to implant placement	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Accidental injection of sodium hypochlorite	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Ov erdose of sedativ es	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Needle stick injuries	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
[Further nev er events added from Phase 1]	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Post-operative stage																
Retained foreign objects after surgical procedures	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Prescription of a drug to a patient with a known allergy to the drug	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	

Candidate never events	Preventable					Serious					Should be classified as a never event					Comments
	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	
Prescription of teratogenic drug to patients known to be pregnant	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
[Further never events added from Phase I]	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	

If you think additional never events should be added. Please fill the following table (add columns if needed):

Additional candidate never event (if needed)	Comments

Once finished, please ensure there are no unanswered items, save the file, and send it to E.Ensaldo-Carrasco@ed.ac.uk

Thank you for your participation

Appendix 21. Second questionnaire

Evidence-based priority setting for patient safety research on never events in ambulatory dental care: Delphi study

Thank you very much for your participation so far in this Delphi study. As you recall, the purpose of this study is to generate an expert consensus-based list of 'never events' in ambulatory dentistry. 'Never events' are defined as serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented.[1]

After having analysed your feedback to the initial list we had compiled, we have refined and updated that initial list. Thanks to your feedback, never events have been added, rephrased or eliminated. We have then developed that updated list into a second questionnaire, so that you can provide us your expert-feedback on this refined list of never events, in accordance with usual iterative Delphi process.

Your responses will be collected and the findings will be again analysed and summarised for you to see. This questionnaire is the second round out of a maximum of three for the study. If needed, your responses will also inform the basis for the third and final questionnaire.

Please try to answer all the included items and, if necessary, comment on how this list can be improved either by modifying, adding or removing items

Thank you.

Reference

1. National Patient Safety Agency. Patient Safety - Never Events: NHS; 2015. Available from: http://www.nrls.npsa.nhs.uk/neverevents/

Instructions: For each candidate 'never event' (ie row), please indicate how strongly you agree/disagree with the three statements about it – that the event is preventable; that it is serious; and finally that it should be classified as a 'never event'. The statements are given in the blue heading row across the top of the table.

The five possible responses for each statement are listed in the cluster of columns below each statement – for each statement there are 5 possible responses, ranging from "strongly disagree" to "strongly agree". This means that you should provide three responses for each candidate never event (row). In addition, you can add a comment in the last column of any row, if you wish.

For each candidate never event (row), you should respond for each statement by either including an "X" mark or highlighting in bold a number between 1 and 5, to indicate the extent of your "disagreement" to "agreement" with that statement.

<u>Please ensure that you have given 3 responses in every candidate event row – one for each statement.</u>

This candidate never event...	... is 'preventable'					... is 'serious'					... should be classified as a 'never event'					Comments
	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	
Candidate never events during...																
... routine assessment																
Failure to implement oral cancer screening as part of the routine assessments	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Failure to refer for oral cancer assessment after patient's lesion do not heal after two weeks of receiving treatment	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Failure to register patient's history of allergies to medication or dental material	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
... preoperative stage																
Mistaken patient identity	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Treatment provided to the wrong patient	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	

This candidate never event...	... is 'preventable'					... is 'serious'					... should be classified as a 'never event'					Comments
	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	
Candidate never events during...																
...preoperative stage *(continued)*																
Failure to prescribe antibiotic prophylaxis before treating patients at risk of developing endocarditis	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Surgical or complex procedure carried out without the voluntary and signed informed consent	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Failure to take pre-operative radiographs for invasive or surgical procedures	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Failure to sterilise re-usable instruments	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
... intraoperative stage																
Use of non-sterilised re-useable instruments	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Use of non-disinfected equipment	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Re-use of disposable items	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Patient's eye injured due to the omission of using appropriate eye protection	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Re-use of damaged endodontic files	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Administration of unlabelled cartridge of local anaesthetics	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Use of dental material in a patient with known history of allergy to the dental material used	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Injection of wrong anaesthetic solution	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	

This candidate never event...	... is 'preventable'					... is 'serious'					... should be classified as a 'never event'					Comments
	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	
Candidate never events during... ... intraoperative stage *(continued)*																
Treatment performed to a patient with a previously known untreated medical condition that can potentially be ex acerbated by the dental treatment	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Ingestion (swallowing) of foreign objects	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Aspiration (inhalation) of foreign objects	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Wrong tooth extracted	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Tooth extraction in a patient that received radiotherapy in the jaw or maxilla	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Extraction in a patient with an non-medically controlled bleeding disorder	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Tooth extraction in a patient treated with bisphosphonates	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Wrong tooth treated (excluding extraction)	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Thermal injury to the pulp for not using irrigation during cavity/crown preparation	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Thermal injury to the soft tissues during the traditional root canal obturation with guttapercha	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Chemical injury by dental material	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Severe apical tooth resorption due to applying heavy forces during orthodontic treatment	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Perforation of the maxillary sinus	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Perforation of the tooth during root canal treatment	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	

This candidate never event...	... is 'preventable'					... is 'serious'					... should be classified as a 'never event'					Comments
	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	Strongly disagree	Disagree	No opinion	Agree	Strongly agree	
Candidate never events during...																
... intraoperative stage *(continued)*																
Nerve damage due to errors in treatment plan	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Intravascular injection of local anaesthetic	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Acrylic set inside the mouth	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Jaw fracture during implant placement due to poor treatment plan	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Jaw fracture during implant placement due to its incorrect placement	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Injection of sodium hypochlorite into surrounding structures during root canal treatment/irrigation	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Overdose of sedatives	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Needle stick injuries	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
... post-operative stage																
Retained foreign objects after surgical procedures (excluding root canal procedures)	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Incorrect medication prescribed to paediatric patients	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Prescription of a drug to a patient with a known allergy to the drug	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Prescription of teratogenic drug to patients known to be pregnant	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	

If you think additional never events should be added, please fill the following table (add rows if needed):

Additional candidate never event (if needed)	Comments

Once finished, please ensure there are no unanswered items, save the file, and send it to E.Ensaldo-Carrasco@ed.ac.uk

Thank you for your participation

Appendix 22. Delphi study participant's feedback summary – Round 2

Evidence-based priority setting for patient safety research on never events in ambulatory dental care: a Delphi study

Dear (Expert's name),

We are grateful for your participation and useful feedback to the second round of this Delphi study. The responses and feedback received in the first round, provided the basis for refining the list of candidate `never events´ (NEs) that were reviewed and scored in the second questionnaire.

We are happy to inform you that we have reached consensus in 24 out of the 43 candidate NEs. Therefore, a third round of questionnaires will not be needed. Below is a summary of the received responses from all the participants compared to your responses. A summary is also included with the overall feedback we received. Thank you for providing your time to help us with our research.

Overall overview of the responses

A total of 32 experts were invited to participate in the second round. Out of these, 29 filled the second questionnaire. After having analysed your responses and feedback we developed a summary of the responses, expressed in medians, and the level agreement between the participants in this study (see Table 1). We estimated your median response considering the three responses given in every candidate NE - that the event is preventable; that it is serious; and finally, that it should be classified as a 'never event.' Any unanswered field was considered as "no opinion." All the candidate 'never events' (NEs) obtained overall median scores equal or greater to 3 corresponding to the responses "no opinion" = 3, "agree" = 4 and "strongly agree" = 5.

Candidate never events during…	Group median response	% of agreement*	Your response**
… routine assessment			
Failure to implement oral cancer screening as part of the routine assessments	5	89.7[A]	5
Failure to refer for oral cancer assessment after patient's lesion do not heal after two weeks of receiving treatment	5	93.1[A]	4
Failure to register patient's history of allergies to medication	5	96.6[A]	5
… pre-operative stage			

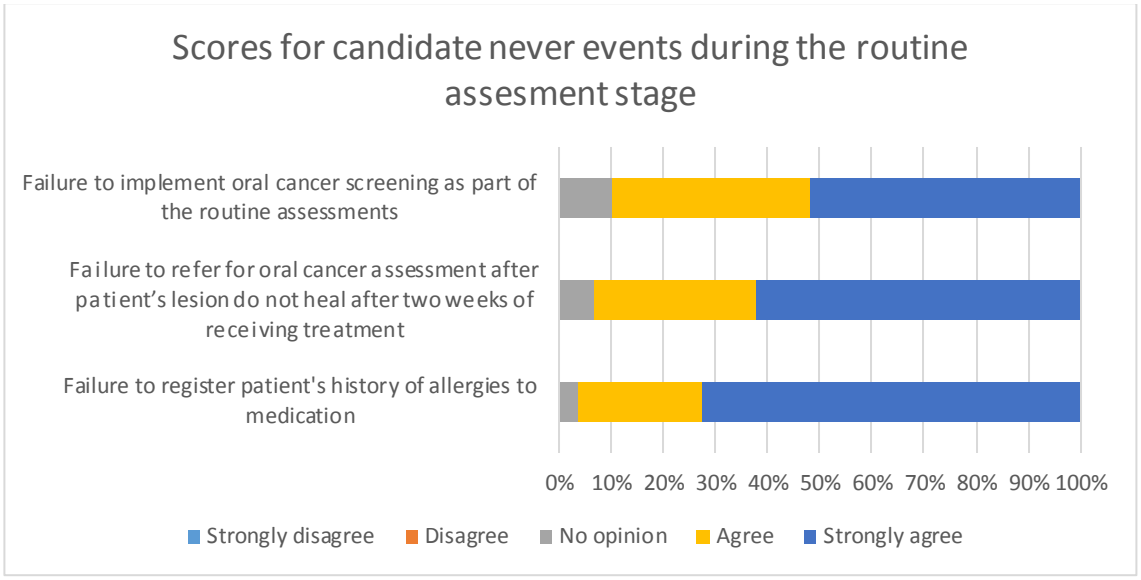
Candidate never events during…	Group median response	% of agreement*	Your response**
Failure to check patient´s identity before implementing a procedure	5	93.1[A]	4
Treatment provided to the wrong patient	5	96.6[A]	4
Failure to prescribe antibiotic prophylaxis before treating patients at risk of developing endocarditis	4	79.3	2
Surgical or complex procedure carried out without the voluntary and signed informed consent	4	79.3	5
Failure to take pre-operative radiographs prior invasive or surgical procedures	4	69.0	4
Failure to sterilise re-usable instruments	5	89.7[A]	5
… intra-operative stage			
Use of non-sterilised re-useable instruments	5	89.7[A]	5
Use of non-disinfected equipment	5	82.8[A]	3
Re-use of disposable items	5	86.2[A]	5
Patient's eye injured due to the omission of using appropriate eye protection	5	89.7[A]	5
Re-use of damaged endodontic files	5	86.2[A]	5
Administration of unlabelled cartridge of local anaesthetics	5	89.7[A]	4
Use of dental material in a patient with known history of allergy to the dental material used	5	89.7[A]	5
Injection of wrong anaesthetic solution	5	86.2[A]	3
Treatment performed to a patient with a previously known untreated medical condition that can potentially be ex acerbated by the dental treatment	5	75.9	1
Ingestion (swallowing) of foreign objects	4	65.5	3
Aspiration (inhalation) of foreign objects	5	86.2[A]	5
Wrong tooth extracted	5	96.6[A]	5
Tooth extraction in a patient that received radiotherapy in the jaw or maxilla	4	65.5	3
Extraction in a patient with a non-medically controlled bleeding disorder	5	79.3	3
Tooth extraction in a patient treated with bisphosphonates	4	62.1	3
Wrong tooth treated (excluding extraction)	4	75.9	4
Thermal injury to the pulp for not using irrigation during cavity/crown preparation	4	75.9	4
Thermal injury to the soft tissues during root canal obturation with guttapercha	4	69.0	3
Chemical injury by dental materials	4	65.5	3
Severe apical tooth resorption due to applying heavy forces during orthodontic treatment	4	79.3	3

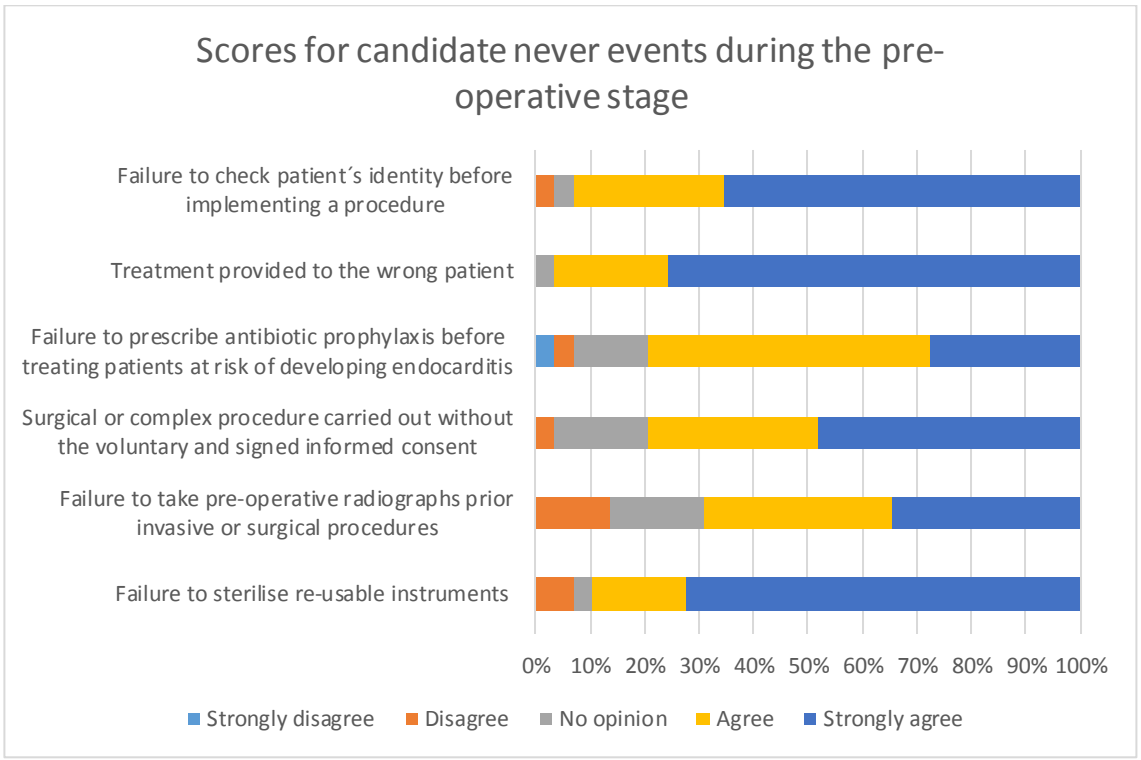
Candidate never events during…	Group median response	% of agreement*	Your response**
Perforation of the maxillary sinus	4	62.1	2
Perforation of the tooth during root canal treatment	4	58.6	3
Nerve damage due to errors in treatment plan	4	79.3	3
Intravascular injection of local anaesthetic	4	62.1	2
Acrylic set inside the mouth	3	48.3	3
Jaw fracture during implant placement due to poor treatment plan	5	89.7[A]	3
Jaw fracture during implant placement due to its incorrect placement	5	89.7[A]	5
Injection of sodium hypochlorite into surrounding structures during root canal treatment/irrigation	5	89.7[A]	4
Overdose of sedatives	5	75.9	3
Needle stick injuries	4	75.9	3
… post-operative stage			
Retained foreign objects after surgical procedures (excluding root canal procedures)	5	89.7[A]	5
Incorrect medication prescribed to paediatric patients	5	89.7[A]	3
Prescription of a drug to a patient with a known allergy to the drug	5	93.1[A]	5
Prescription of teratogenic drug to patients known to be pregnant	5	93.1[A]	5

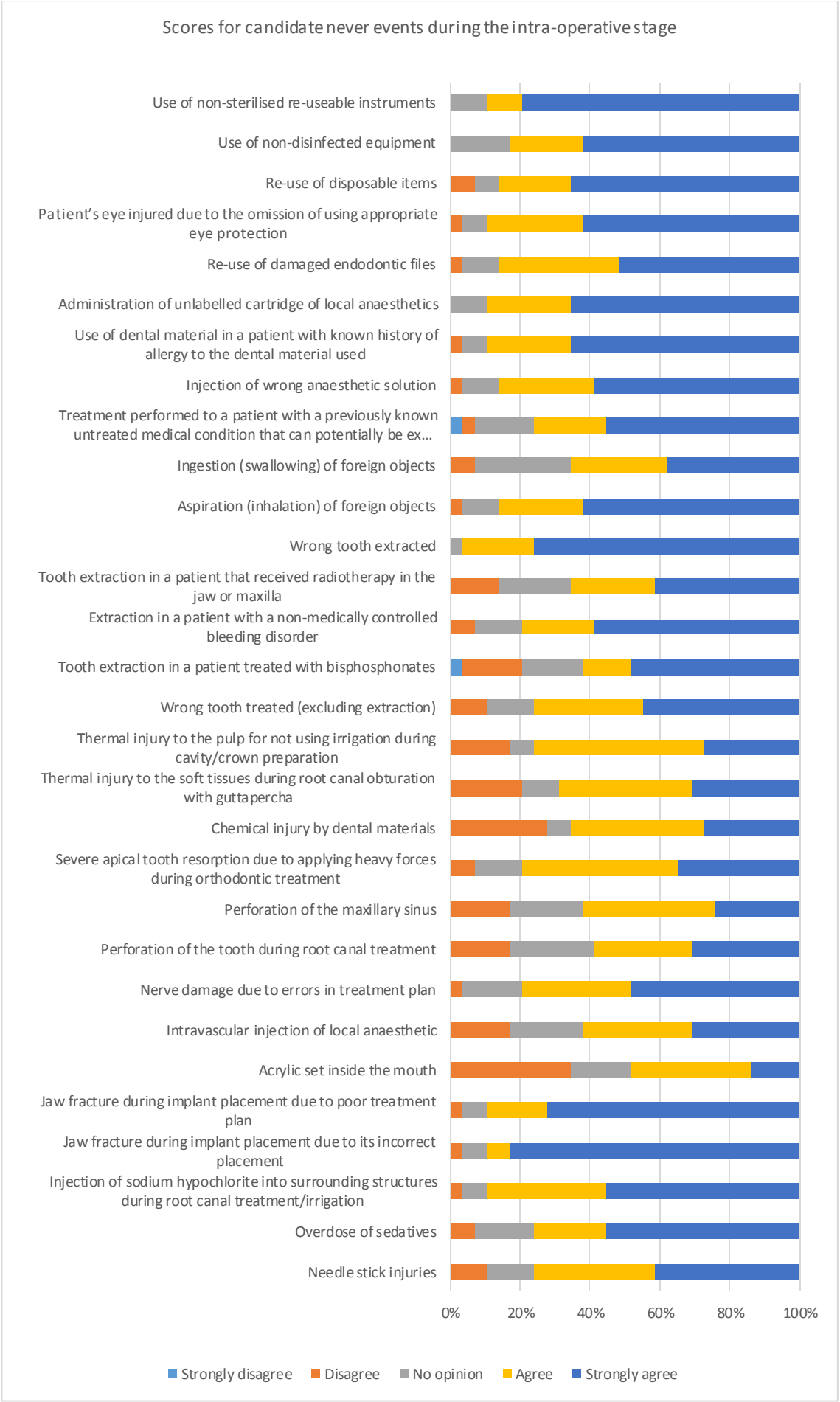
***(agree + strongly agree)**
****expressed as the median calculated from your three responses in every candidate never event**
[A]agreement reached

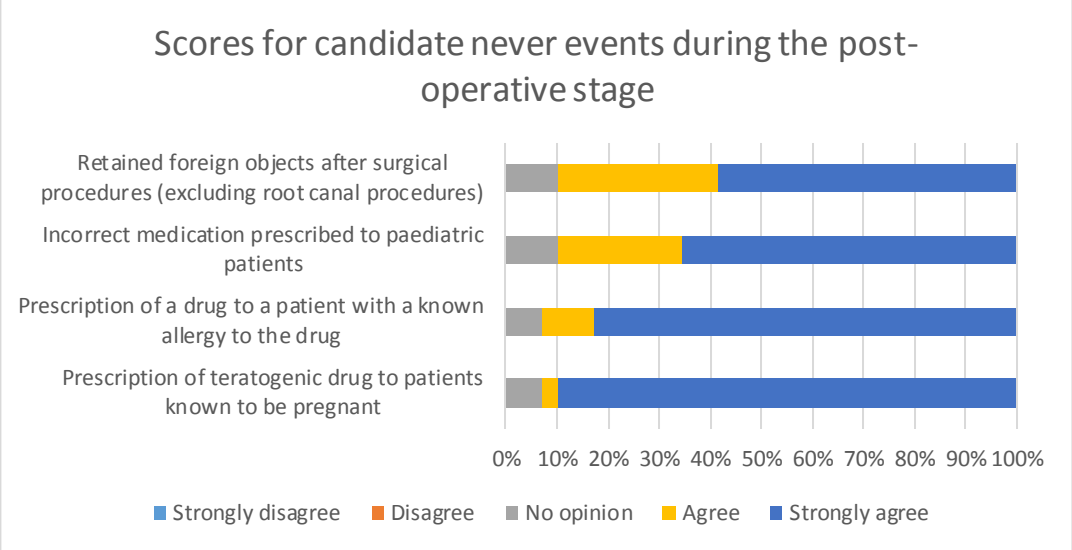
What do the results shown in Table 1 mean?

The results displayed in Table 1 show that consensus was achieved in 24 out of the 43 candidate NEs. To bring more clarity, we have further displayed the distribution of scores assigned for the candidate NEs during the routine assessment stage and preoperative staged (Figure 1), the intraoperative stage (Figure 2) and postoperative stage (Figure 3).


Scores for candidate never events during the routine assesment stage
Failure to implement oral cancer screening as part of the routine assessments
Failure to refer for oral cancer assessment after patient's lesion do not heal after two weeks of receiving treatment
Failure to register patient's history of allergies to medication
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
Strongly disagree
Disagree
No opinion
Agree
Strongly agree


Scores for candidate never events during the pre-operative stage
Failure to check patient´s identity before implementing a procedure
Treatment provided to the wrong patient
Failure to prescribe antibiotic prophylaxis before treating patients at risk of developing endocarditis
Surgical or complex procedure carried out without the voluntary and signed informed consent
Failure to take pre-operative radiographs prior invasive or surgical procedures
Failure to sterilise re-usable instruments
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
Strongly disagree
Disagree
No opinion
Agree
Strongly agree


Scores for candidate never events during the intra-operative stage
Use of non-sterilised re-useable instruments
Use of non-disinfected equipment
Re-use of disposable items
Patient's eye injured due to the omission of using appropriate eye protection
Re-use of damaged endodontic files
Administration of unlabelled cartridge of local anaesthetics
Use of dental material in a patient with known history of allergy to the dental material used
Injection of wrong anaesthetic solution
Treatment performed to a patient with a previously known untreated medical condition that can potentially be ex...
Ingestion (swallowing) of foreign objects
Aspiration (inhalation) of foreign objects
Wrong tooth extracted
Tooth extraction in a patient that received radiotherapy in the jaw or maxilla
Extraction in a patient with a non-medically controlled bleeding disorder
Tooth extraction in a patient treated with bisphosphonates
Wrong tooth treated (excluding extraction)
Thermal injury to the pulp for not using irrigation during cavity/crown preparation
Thermal injury to the soft tissues during root canal obturation with guttapercha
Chemical injury by dental materials
Severe apical tooth resorption due to applying heavy forces during orthodontic treatment
Perforation of the maxillary sinus
Perforation of the tooth during root canal treatment
Nerve damage due to errors in treatment plan
Intravascular injection of local anaesthetic
Acrylic set inside the mouth
Jaw fracture during implant placement due to poor treatment plan
Jaw fracture during implant placement due to its incorrect placement
Injection of sodium hypochlorite into surrounding structures during root canal treatment/irrigation
Overdose of sedatives
Needle stick injuries
0%
20%
40%
60%
80%
100%
Strongly disagree
Disagree
No opinion
Agree
Strongly agree



Feedback received

For the refined list of candidate NEs were eliminated or rephrased in line to the comments and suggestions received in the first questionnaire. We have synthesised these for you to read (see Table 2). Your individual responses are being kept confidential to the research team.

Candidate never events during…	Summary of comments
… routine assessment	
Failure to implement oral cancer screening as part of the routine assessments	The population of patients targeted might be considered, particularly in patients with elevated risk for developing oral cancer. Patients with less risk, such as children, may not be considered for oral cancer routine assessments.
Failure to refer for oral cancer assessment after patient's lesion do not heal after two weeks of receiving treatment	There are a variety of lesions and types of treatments for them. Any oral cancerous lesion should be treated immediately. The time for referring a non-healing lesion may vary between two to three weeks.
Failure to register patient's history of allergies to medication	When filling the medical history, we assume that the patient is providing accurate and relevant details about allergies.
… pre-operative stage	
Failure to check patient´s identity before implementing a procedure	No comments received
Treatment provided to the wrong patient	No comments received

Failure to prescribe antibiotic prophylaxis before treating patients at risk of developing endocarditis	Participants report that current recommendations or guidelines vary between countries. In some countries, the prescription of antibiotic prophylaxis before treating patients at risk of developing endocarditis may not be compulsory and may be up to the dentist to decide.
Surgical or complex procedure carried out without the voluntary and signed informed consent	Dentists need to make sure patients are well informed about the treatment and the potential risks. In the case of emergencies or when a patient cannot communicate, dentists need to obtain the informed consent of a parent, guardian or relative. Some of these events may occur when dentists encounter life-threatening emergencies.
Failure to take pre-operative radiographs prior invasive or surgical procedures	Equipment may not be available in some countries´ dental practice. On the one hand, dentists may no take pre-operative radiographs for non-invasive or non-surgical procedures. In some other instances, patients may not allow radiographs to be taken.
Failure to sterilise re-usable instruments	No comments received
… intra-operative stage	
Use of non-sterilised re-useable instruments	These instruments can be subjected to high-level disinfection as an alternative. However, some participants commented that a mixing spatula might not be necessarily sterilised before using it in another patient. Also, participants in some countries report that, instead of sterilization, high-speed handpiece disinfection is still a common procedure. A similar approach is common for re-using irrigation syringes during root canal treatment.
Use of non-disinfected equipment	It depends on the type of equipment. Dental equipment that has no direct contact with patients may not be necessary to be disinfected.
Re-use of disposable items	It depends on the type of item re-used. For instance, disposable spatulas for mixing cement can be re-used after being subjected to high-level disinfection.
Patient's eye injured due to the omission of using appropriate eye protection	No comments received
Re-use of damaged endodontic files	No comments received
Administration of unlabelled cartridge of local anaesthetics	No comments received
Use of dental material in a patient with known history of allergy to the dental material used	In some cases, patients may not be aware of any history of allergies to dental materials.

Injection of wrong anaesthetic solution	No comments received
Treatment performed to a patient with a previously known untreated medical condition that can potentially be ex acerbated by the dental treatment	This never event may need further clarification as variables such as the type of treatment and/or medications administered need to be considered.
Ingestion (swallowing) of foreign objects	The potential for serious harm because of swallowing foreign objects can depend on the size and material accidentally ingested. In some cases, these events cannot be avoided even if appropriate preventive measures are taken.
Aspiration (inhalation) of foreign objects	In some cases, these events cannot be avoided even if appropriate preventive measures are taken
Wrong tooth extracted	A wrongly extracted tooth should be a never event. The potential to cause serious harm may depend on the tooth extracted (e.g. molar, premolar or canine) and the subsequent consequences on the patients' oral health, oral function and/or aesthetics.
Tooth extraction in a patient that received radiotherapy in the jaw or maxilla	Different comments were recorded. First, this procedure can be carried out after having a comprehensive discussion of the risks and benefits with the patient. Secondly, the procedure can be performed after appropriate management and consultation with a physician.
Extraction in a patient with a non-medically controlled bleeding disorder	The procedure can be performed after appropriate management and consultation with a physician.
Tooth extraction in a patient treated with bisphosphonates	The procedure can be performed after having appropriate management and consultation with a physician as bisphosphonates can be administered by oral route or intravenous route. Patients taking oral bisphosphonates may have lower risk than the ones having it by the intravenous route. In some instances, endodontic treatment may be a better alternative, even if the tooth cannot be fully restored.
Wrong tooth treated (excluding extraction)	This event needs more clarity as there is a variety of treatment with varying degrees of potential harm.
Thermal injury to the pulp for not using irrigation during cavity/crown preparation	No comments received

Thermal injury to the soft tissues during root canal obturation with guttapercha	The degree of harm may depend on the extent of the injury and the areas of soft tissues involved.
Chemical injury by dental materials	The degree of harm may depend on the type of chemical that caused harm. Also, the extent of the injury and the areas of soft tissues involved
Severe apical tooth resorption due to applying heavy forces during orthodontic treatment	No comments received
Perforation of the maxillary sinus	A more detailed description may be needed. Even with appropriate preventive measures, the perforation of the maxillary sinus might still happen. Failure to inform the patient or to follow up may be more critical.
Perforation of the tooth during root canal treatment	The degree of harm may depend on the size, location, management and follow-up. In dental school, it is an event challenging for students to prevent.
Nerve damage due to errors in treatment plan	Nerve damage occurs during the intraoperative stage. It may not necessarily be a consequence of flaws when developing a treatment plan.
Intravascular injection of local anaesthetic	This event can be potentially serious in a patient with pre-existing medical conditions.
Acrylic set inside the mouth	This item is not clear
Jaw fracture during implant placement due to poor treatment plan	No comments received
Jaw fracture during implant placement due to its incorrect placement	No comments received
Injection of sodium hypochlorite into surrounding structures during root canal treatment/irrigation	This event can be prevented if appropriate measures are taken. Other variables, such as the morphology of the root canal, can increase the chance for this even to happen.
Overdose of sedatives	This event can still happen even if appropriate preventive measures are taken. In some countries, patients can get access to medications without a medical prescription. Failure to identify signs and symptoms of potential overdose is also critical.
Needle stick injuries	Failure to conduct the appropriate steps during the administration of local anaesthetic would be better.
… post-operative stage	

Retained foreign objects after surgical procedures (excluding root canal procedures)	No comments received
Incorrect medication prescribed to paediatric patients	The potential to cause harm varies. However, this event can be expanded to all patients instead of paediatric patients. Also, the erroneous dose is inappropriate.
Prescription of a drug to a patient with a known allergy to the drug	No comments received
Prescription of teratogenic drug to patients known to be pregnant	A classification system for assessing the degree of teratogenicity should be used

Appendix 23. Delphi study participant's feedback summary – Round 1

Evidence-based priority setting for patient safety research on never events in ambulatory dental care: a Delphi study

Dear (Expert's name),

Thank you for your participation and very helpful feedback to the first round of this Delphi study. Below is a summary of the received responses of the other participants compared to your own responses. You will also see a summary of the feedback we received. Please use this information to score your answers again in the second round. Thank you for giving your time to help us with our research. Your participation for the second round is very important to ensuring a valid result, and we look forward to receive your answers and feedback.

Overall overview of the responses

A total of 41 experts were invited to participate in the study. Out of these, 32 agreed after having provided their informed consent and filled the first questionnaire. After having analysed your responses and feedback we developed a summary of the responses, expressed in medians, and the level agreement between the participants in this study (see Table 1). We estimated your median response taking into account the three responses given in every candidate ´never event´ - that the event is preventable; that it is serious; and finally that it should be classified as a 'never event.' Any unanswered field was considered as "no opinion." All the candidate 'never events' (NEs) obtained overall median scores equal or greater to 3 corresponding to the responses "no opinion" = 3, "agree" = 4 and "strongly agree" = 5.

Table 1. Overall 'expert' median scores for all potential never events

Candidate never events during…	Group median response	Percentage of agreement	Your response**
…routine assessment			
Missed diagnosis of oral cancer	4	59.4	5
Delayed referral of patient with clinical suspicion of cancer	5	68.8	5
…pre-operative stage			
Mistaken patient identity	5	71.9	5
Failure to prescribe antibiotic prophylaxis before treating root canal infections	3	37.5	1
Procedure carried out without the voluntary and signed informed consent	4	53.2	5

Candidate never events during…	Group median response	Percentage of agreement	Your response**
…intra-operative stage			
Use of non-sterile instruments or equipment	5	75.0	5
Use of dental material in a patient with known history of allergy to the dental material used	5	78.1	5
Use of outdated material	3.5	50.0	4
Administration of unlabeled cartridge of local anesthetics	5	68.8	5
Injection of wrong anesthetic solution	5	75.0	5
Treatment performed to a patient with a previously known untreated medical condition that can potentially be ex acerbated by the dental treatment	4.5	68.8	5
Ingestion or aspiration of foreign objects	4	68.8	5
Wrong tooth treated or extracted	5	75.0	5
Severe apical tooth resorption due to orthodontic treatment	3	46.9	4
Nerve damage due to errors in treatment plan	4	65.6	5
Intravascular injection of local anesthetic	3	43.8	5
Acrylic set inside the mouth	4	53.1	5
Jaw fracture due to implant placement	4	68.7	5
Accidental injection of sodium hypochlorite	5	68.7	5
Overdose of sedatives	4	59.4	5
Needle stick injuries	4	68.8	5
…post-operative stage			
Retained foreign objects after surgical procedures	5	65.6	5
Prescription of a drug to a patient with a known allergy to the drug	5	78.1	5
Prescription of teratogenic drug to patients known to be pregnant	5	75.0	5

***(agree + strongly agree)**

****expressed as the median calculated from your three responses in every candidate never event**

What do the results shown in Table 1 mean?

The results displayed in Table 1 show that, no agreement was reached in the first round in this Delphi

study. In order to bring more clarity, we have further displayed the distribution of scores assigned for the candidate NEs at the routine assessment and preoperative staged (Figure 1), the intraoperative stage (Figure 2) and postoperative stage (Figure 3).

As shown in these, a reason for not reaching a consensus is due to the number of scores under the "no opinion" label. This was later understood after analysing your feedback as we were able to identify that some of candidates NEs that needed more clarity and further refinement. Therefore, your responses and feedback have provided the basis for refining the list of candidate NEs for you to review and score in the second questionnaire.

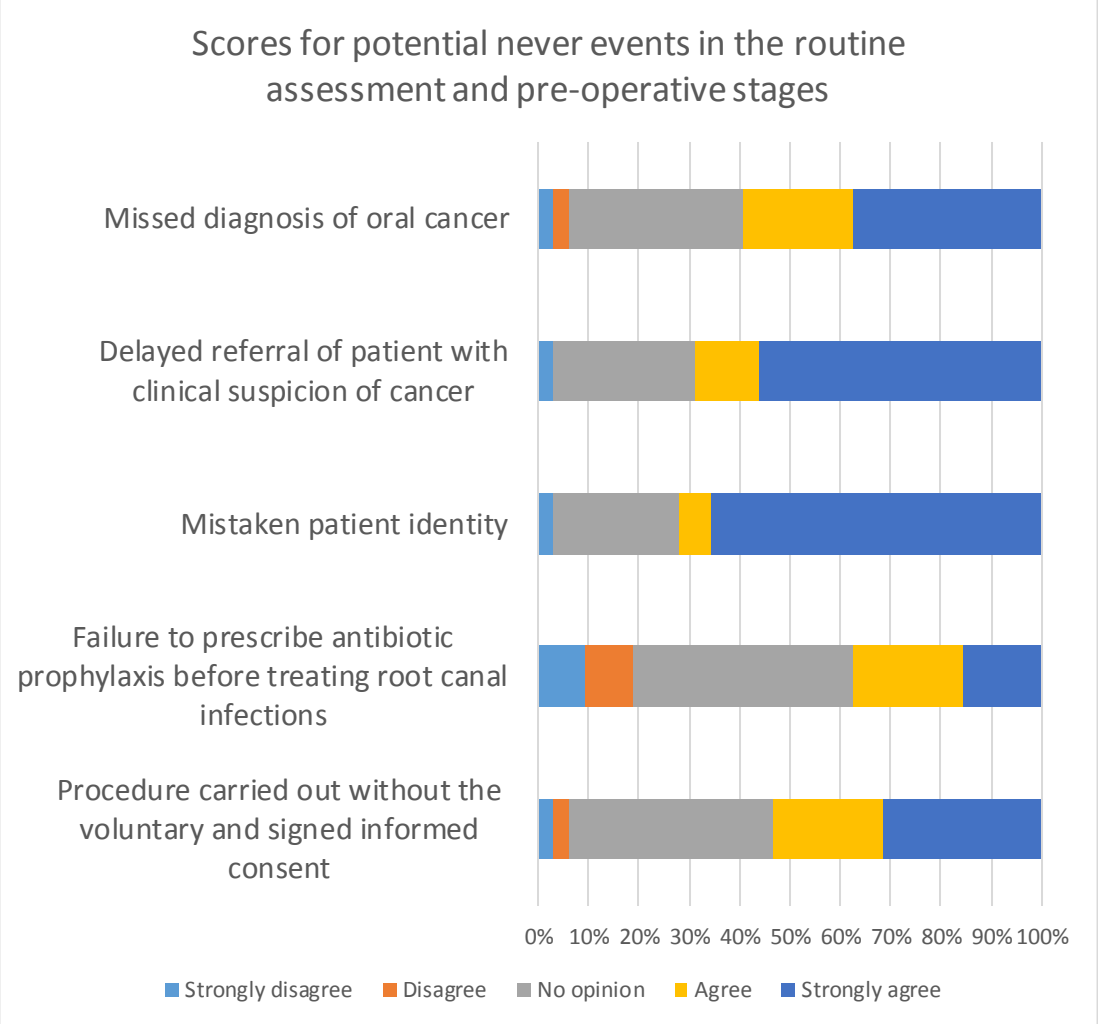


Figure 1. Score distribution for potential never events in the routine assessment and pre-operative stages

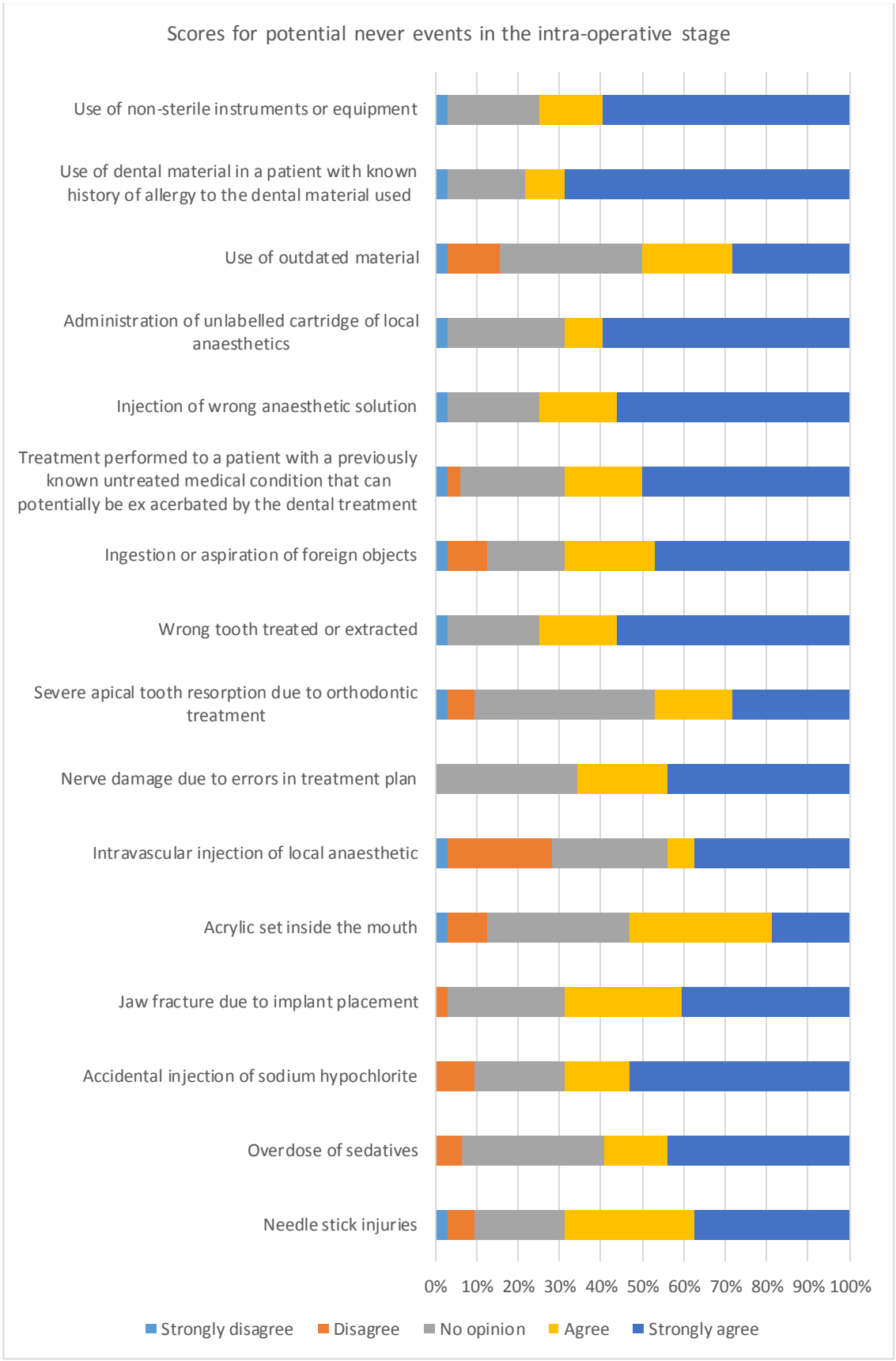


Figure 2. Score distribution for potential never events in the intraoperative stage

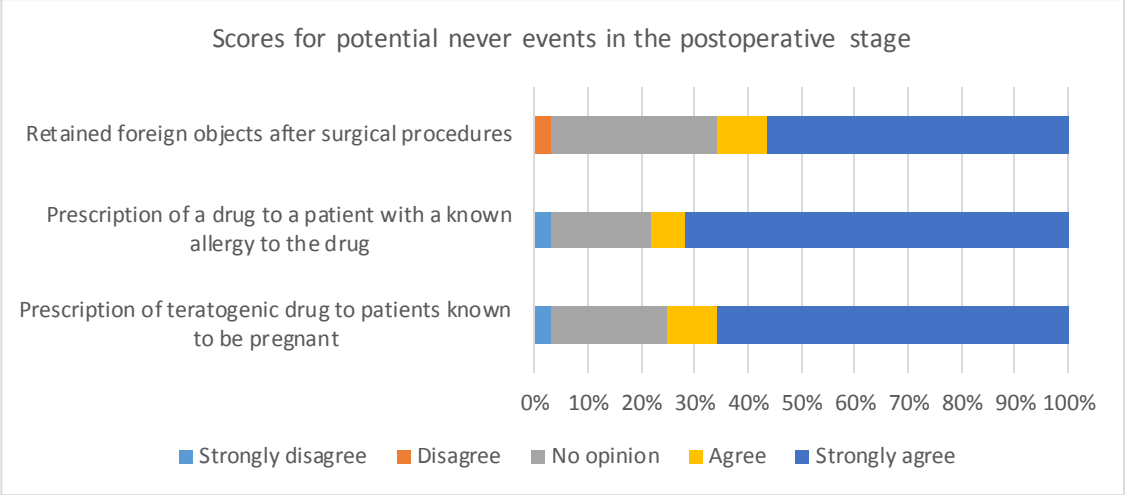


Figure 3. Score distribution for potential never events in the post-operative stage

Feedback received. For the second round, candidate NEs were eliminated or rephrased in line to the comments and suggestions received in the first questionnaire. We have synthesised these for you to read and consider for scoring the candidate NEs contained in the second questionnaire (see Table 2). Your individual responses are being kept confidential to the research team.

Table 2. Summary of the feedback received in the first questionnaire

Stage	Summary of comments
Routine assessment	
Missed diagnosis of oral cancer	Oral cancer diagnosis, particularly in early stages, can be challenging task as the potentially cancerous lesions can be misdiagnosed as other benign and more common lesions of the oral mucosa. Moreover, patients with a greater risk for developing oral cancer are less likely to attend dental practices for routine check-ups
Delayed referral of patient with clinical suspicion of cancer	In order to consider it as a never event, the nature of the signs and symptoms need to be considered. Examples include failure to refer after ulcers do not heal after receiving treatment
Preoperative stage	
Mistaken patient identity	It would be better to classify it as "Treatment provided to the wrong patient"
Failure to prescribe antibiotic prophylaxis before treating root canal infections	Antibiotic prophylaxis may not be always necessary and may also not be a standardised practice among different countries. It also depends of the purpose of the antibiotic prophylaxis itself. In some cases, it is recommended to prevent local infection, but also it can be recommended in medically compromised. For example, in patients at risk of developing endocarditis.
Procedure carried out without the voluntary and signed informed consent	It depends of the procedure as for minor procedures, which do not involve painful and/or invasive procedures, the verbal consent mat be enough. Moreover, we need to also assume that the patient should have the capacity to provide consent.

Stage	Summary of comments
Intra-operative stage	
Use of non-sterile instruments or equipment	A difference needs to be considered between sterile instruments and sterile equipment. Dental instruments can be either sterilised or subjected to high-level disinfection. This also leads to the way in which sterile and non-sterile instruments is stored for future use.
Use of dental material in a patient with known history of allergy to the dental material used	Registering any history of allergy is a mandatory task during medical history taking
Use of outdated material	It appears that outdates material can be used. As long as there is no apparent high risk for using outdate dental material, it can still be used.
Administration of unlabelled cartridge of local anaesthetics	The labels for local anaesthesia cartridges can vary from countries and brand. Some of them can have stamps while other have the contents stamped directly on the glass.
Injection of wrong anaesthetic solution	It depends of the patient
Treatment performed to a patient with a previously known untreated medical condition that can potentially be ex acerbated by the dental treatment	It depends of the medical condition. Also, emergency dental treatments should be considered to make a distinction between routine treatment and emergency treatments.
Ingestion or aspiration of foreign objects	A distinction needs to be made between ingestion as aspiration. Ingestion can be potentially serious, however, aspiration is inevitably a serious event, It is a risk as most of the treatments are performed in the patients' mouth.
Wrong tooth treated or extracted	A distinction needs to be made between "extraction" and "treated." When a wrong tooth is extracted, the outcome is irreversible. However, for minor procedures, the outcome may not be irreversible.
Severe apical tooth resorption due to orthodontic treatment	The use of heavy forces can result in severe apical resorption, however, also minor forces can make it happen.
Nerve damage due to errors in treatment plan	It should be modified to "permanent nerve damage due to errors in treatment plan" Nerve damage can also happen due to poor anaesthetic administration techniques.
Intravascular injection of local anaesthetic	This event, when it happens, usually has a temporary effect. Moreover, instruments that can aid the dentist to prevent it such as aspirating syringes, may not be available in all countries. Also, this event is potentially difficult to prevent in students.
Acrylic set inside the mouth	This event need further clarification. Also, in some countries, this technique is no further used

Stage	Summary of comments
Jaw fracture due to implant placement	Jaw fracture is a risk related to implant placement. However, it would not occur if the treatment planning was poor or flaws during its placement occurred.
Accidental injection of sodium hypochlorite	This event needs rewording as it does not clarify if the sodium hypochlorite makes contact with the soft tissues during irrigation of root canals.
Overdose of sedatives	The decision to consider this event as a never event depends on the extent of the overdose. Also, the consequences or degree of resulting harm need to be considered.
Needle stick injuries	No comments received
Intra-operative stage	
Retained foreign objects after surgical procedures	In order to consider it as a NE, particularly in it seriousness and preventability, it depends on the type of retained object. For instance, endodontic files that break during root canal treatments can be left inside the tooth without apparent complications. Moreover, other materials like root canal sealing cements can be extruded beyond the apex and thus, retained.
Prescription of a drug to a patient with a known allergy to the drug	No comments received
Prescription of teratogenic drug to patients known to be pregnant	No comments received